

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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In re SANOFI-AVENTIS SECURITIES	:	Civil Action No. 1:07-cv-10279-GBD
LITIGATION	:	
	:	<u>CLASS ACTION</u>
	:	
This Document Relates To:	:	ECF CASE
	:	
ALL ACTIONS.	:	CONSOLIDATED COMPLAINT FOR
	:	VIOLATIONS OF SECURITIES LAWS
	:	
	:	<u>DEMAND FOR JURY TRIAL</u>
	:	
	X	

INTRODUCTION AND OVERVIEW

1. Lead Plaintiffs, City of Edinburgh Council of the Lothian Pension Fund and New England Carpenters Guaranteed Annuity Funds (collectively referred to as “plaintiffs”), on behalf of themselves and all other persons similarly situated, allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys.

NATURE OF THE ACTION

2. This is a federal securities class action brought against sanofi-aventis (“Sanofi” or the “Company”) and certain of its officers for violations of the Securities Exchange Act of 1934 (the “Exchange Act”). This action is brought on behalf of: (a) all United States-based purchasers of Sanofi securities on the New York Stock Exchange (“NYSE”); (b) all United States-based purchasers of Sanofi securities on any foreign exchange; and (c) all foreign purchasers of Sanofi securities on the NYSE, during the period March 1, 2005 through June 13, 2007 (the “Class Period”), who were damaged as a result of defendants’ violations of federal securities laws.

Rimonabant and Obesity

3. This action concerns defendants’ false and misleading statements and omissions regarding the development of the drug rimonabant and Sanofi’s New Drug Application (“NDA”) filed with the United States Food and Drug Administration (“FDA”) for the use and promotion of rimonabant as treatment for obesity in the United States. Sanofi markets rimonabant as “Acomplia” in Europe and proposed marketing the drug under the trade name “Zimulti” in the United States. Rimonabant is classified as a Cannaboid 1 (“CB-1”) Receptor Antagonist/Inverse Agonist. In lay terms, the compound directly affects the brain’s hunger signal – thereby reducing the craving for food.

4. Prior to the Class Period, defendants conducted four phase III trials of rimonabant tolerability and efficacy in treating obesity, also known as the Rimonabant In Obesity studies (“RIO Studies”). The Company had also completed at least eight additional clinical studies of rimonabant as a treatment for other indications, including alcoholism, schizophrenia and smoking, prior to the Class Period. By the time Sanofi completed those studies, the Company had invested several years and tens, if not hundreds, of millions of dollars to develop the drug and prepare it for marketing in the United States and around the globe.

5. As a CB-1 receptor drug that acts directly on the brain’s hunger signal, as opposed to compounds that act as mere stimulants (*e.g.*, Fen-Phen), rimonabant was considered to be a “first-in-class” weight-loss drug. Accordingly, prior to and throughout the Class Period, defendants positioned rimonabant in the United States as the first “magic pill” that would help people shed pounds without serious side effects. Had defendants’ claims been true and the FDA approved the drug for use in the United States, Sanofi was set to reap an astronomical windfall. During the Class Period, analysts estimated Sanofi’s annual sales of rimonabant could exceed €3.2 billion by 2011. Throughout the Class Period, however, defendants failed to disclose to investors that clinical study data revealed that rimonabant caused suicidal ideation and depression. “Suicidal ideation” is a common medical term for thoughts about suicide, from fleeting suicidal thoughts to detailed planning and even unsuccessful attempts (whether intended to fail or to succeed). In the rimonabant studies, suicidal ideation was specifically tracked and characterized as a serious adverse event.

6. The market for weight loss treatments is enormous for the simple reason that obesity has reached epidemic proportions and is a major health concern in the United States. Nearly 30% of the United States population is obese and over 60% of the population is either overweight or obese. The combination of those facts with the \$33 billion total market for weight loss treatments meant

that rimonabant had the potential to be a truly gargantuan “blockbuster” drug. Moreover, because rimonabant is a treatment for a chronic condition, FDA approval for this “first-in-class” drug would have resulted in an immediate and long-lasting revenue stream for Sanofi. Accordingly, prior to and during the Class Period, the defendants pitched rimonabant to investors and patients as a wonder drug with far-reaching benefits, yet devoid of any significant risk.

FDA Approval of Rimonabant Was Critically Important to Sanofi

7. Sanofi, like other pharmaceutical companies, is a research-driven company and its business model depends on the development and regulatory approval of new, patent-protected products to replace other brand-name drugs as they come off patent. In the pharmaceutical industry, this is referred to as the “drug pipeline.” The drug pipeline is critical to pharmaceutical companies’ financial successes and important to investors because new drug products are necessary to sustain growth and profitability. Many research-driven pharmaceutical companies that have experienced difficulties maintaining a full pipeline in the last decade have seen their valuation tumble or have resorted to alternatives to product development to fill pipeline gaps. Alternatives include buying new drugs for the pipeline through the purchase of whole pharmaceutical and biotech companies or licensing promising or already approved drugs. For instance, Sanofi was rumored to be acquiring biotech giant ImClone in late 2006, and has made more than 100 collaborative agreements with small biotech companies and other partners. This trend continued after the Class Period, as Sanofi bought a 19% stake in the large biotech firm Regeneron in November 2007 in order to seal joint drug development programs.

8. By the beginning of the Class Period, Sanofi, as well as its competitors, were operating in a climate where markedly fewer drugs had been approved between 2000 and 2005, as compared to the five years prior. Moreover, regulatory authorities around the globe were rejecting far more drugs in the later stages of development than ever before. This phenomenon is well known,

has been widely discussed in the media, and has been a major issue for all pharmaceutical companies. In the pharmaceutical industry, it is most often referred to as the “pipeline problem.”

9. Another phenomenon, which aggravates the “pipeline problem,” are drugs that are scheduled to roll “off patent” or are otherwise challenged by competitors as no longer deserving of patent protection. Once a company’s drugs go off patent, competitors can market generic versions. Generics can be sold at a fraction of the cost of brand-name drugs because their manufacturers do not have to recoup all of the R&D and marketing costs already invested by the holder of the expired patent. A drug which was worth a billion dollars in revenue each year under patent may be worth only a few million per year once there are generic competitors.

10. Before and during the Class Period, Sanofi was considered by analysts as having one of the highest off patent exposure risks in the pharmaceutical industry. For example, Sanofi was scheduled to lose patent protection for several of its blockbuster drugs by 2012, including Ambien, Plavix and Lovenox, which combined for revenues exceeding \$6.0 billion in 2005. Additionally, Sanofi was dealing with a number of cases challenging the patent protection for both Plavix and Lovenox, which defendants identified as potential material adverse events that could affect financial guidance provided to analysts and investors.

11. During 2005, Plavix was one of Sanofi’s largest products in terms of sales volume, with worldwide net sales of approximately \$2.0 billion. In November 2001, Apotex Inc. (“Apotex”) filed an Abbreviated New Drug Application (“ANDA”) with the FDA to seek approval to market a generic version of Plavix. Apotex also challenged the validity of a key Plavix patent which was otherwise set to expire on November 17, 2011. In response, Sanofi filed a patent infringement suit in the United States District Court for the Southern District of New York, and the filing of that action triggered an automatic stay barring the FDA from approval of Apotex’s ANDA for 30 months. The

case was a rollercoaster for all parties involved, as several settlements were reached and rejected. Apotex was even allowed to market generic Plavix for a period of time while the parties litigated the case. Three other pharmaceutical companies joined the melee and also filed suit to challenge the validity of the Plavix patent. The court did not rule on the matter until June 19, 2007, and, throughout the Class Period, securities analysts covering Sanofi repeatedly asserted that the Plavix litigation hung like a dark cloud over the Company's future revenue streams.

12. During 2005, Lovenox was Sanofi's largest product in terms of sales volume, accounting for approximately \$2.1 billion in net sales. Since its launch, Lovenox had become the leading anti-blood clotting drug in the world. In anticipation of the December 2004 expiration of Sanofi's Lovenex patent and in order to protect this prized source of revenue and profits, on February 19, 2003, Sanofi filed a "citizens petition" with the FDA asking it not to approve generic versions of Lovenox. Four months later, two of Sanofi's competitors, Amphastar Pharmaceuticals, Inc. ("Amphastar") and Teva Pharmaceutical Industries Ltd. ("Teva"), asked for FDA approval to market generic versions of the drug in the United States. This development commenced heated patent litigation between Sanofi and its generic rivals. This case also triggered a 30-month stay on generic approval.

13. In June 2005, the Lovenox patent case was heard in the United States District Court for the Southern District of California. The court ruled in favor of Amphastar and Teva, holding that Sanofi's Lovenox patent was invalid. Sanofi immediately appealed the trial court's ruling, thereby maintaining the protection of the 30-month stay. In August 2005, the attack on the Company's golden goose continued when a third company, Momena Pharmaceuticals, Inc., applied to the FDA for approval to market generic Lovenox. On appeal, the Ninth Circuit ruled that summary judgment against Sanofi was inappropriate and the case was remanded back to the trial court to be heard by a

different judge. In February 2007, the trial court reaffirmed that Sanofi's Lovenox patent was invalid.

14. In light of Sanofi's patent woes during the Class Period, FDA approval of rimonabant for an obesity indication was critical to investors. Disclosure of the causal connection between use of the drug and suicidality and serious psychiatric adverse events, which were known by defendants prior to and throughout the Class Period, would not only have destroyed the Company's weight loss treatment franchise, but magnified the market's concern about Sanofi's drug pipeline.

15. Indeed, both before and after receiving the FDA approvable letter in February 2006 – which, unbeknownst to investors, requested that the Company submit additional safety data and analysis to address rimonabant's association with suicidality and depression – defendants continued touting the compound as safe for patients in the United States market. For example, on February 24, 2006 defendants emphasized to analysts and investors the enormous market potential for rimonabant in the United States – ***“100 [million] Americans . . . are considered to suffer from abdominal obesity”*** – and reassured investors that the drug would help millions of patients suffering from multiple cardio-metabolic risk factors associated with abdominal obesity. On the same day, defendants added, ***“we got some great data on the RIO program [and] its about our ambition, ambition to deliver and do the best for, not only the product but, obviously, for the patient.”***

16. The *Wall Street Journal* subsequently reported:

IN THE EARLY EVENING of Friday, Feb. 17, French pharmaceuticals giant Sanofi-Aventis SA said it had received from the [FDA] a letter saying the regulator would approve Sanofi's weight-loss drug only if the company could meet certain conditions.

[On February 19, 2007] Sanofi's investor-relations department took calls from research analysts who follow the company closely. The company officials passed on a crucial piece of intelligence about the drug's future prospects [*i.e.*, that Sanofi expected the FDA to approve rimonabant by the second half of 2006].

* * *

Sanofi's shares fell 3.1% that Monday, to 71.70 Euros (\$84.95) – a significant drop, but not as much as they might have fallen had the company not reassured some investors about its most important new drug.

17. On May 5, 2006, defendant Spek responded to questions from analysts regarding the launch date for rimonabant in the United States, stating:

[SPEK] *On Acomplia, I think we can say absolutely nothing else. We remain confident and prepared to launch Acomplia during the second half of 2005 – in 2006, excuse me. We remain in a permanent exchange with the FDA.*

* * *

[SPEK] *On Acomplia, we don't intend to increase our rep sales force inside Europe consequent to the imminent launch, except perhaps small increases in smaller markets. But in the major markets we do this with our existing forces.*

Then, on the ongoing conversations with the FDA, I cannot confirm to you that we had one meeting, as your question has been posed. I said earlier that we are in a permanent dialogue with the agency and I have nothing to add to this. ***But as also previously stated, yes, we are still planning and we continue to plan for a launch also in the U.S. in the second half of 2006.***

18. In May 2006, a Natexis Bleichroeder analyst expressed the importance of rimonabant for Sanofi's financial outlook and repeated defendants' statements that the drug would be approved in late 2006: ***"The most important catalyst, in our view, should be the final green light for Acomplia in the U.S., expected in H2."***

19. A Bernstein Research analyst expressed high expectations for rimonabant in May 2006 as well:

We believe Acomplia (obesity) is en route to mega-blockbuster status and expect associated regulatory events, along with better market appreciation of recent catalysts, to potentiate excess returns for the remainder of 2006.

* * *

Because of the vastness of the targeted therapeutic markets – obesity management, diabetes, and dyslipidemia – and the lack of safe, tolerable and effective products for obesity, we believe Acomplia has a clear path to becoming one of the world's largest drugs.

* * *

We believe the signals to date confirm our extensive research which suggests that Acomplia could be one of the most commercially successful drugs in history.

* * *

Sanofi-Aventis has not disclosed the contents of the approvable letter but expects approval within “months.”

20. While the Plavix and Lovenox litigation was ongoing, Sanofi raised additional pipeline concerns by selling off its share of world-wide rights to one of its most promising drugs, Exubera. Indeed, Sanofi was poised to become even more reliant on rimonabant to buoy the Company's revenues in the long-term. As an analyst for Independent International Investment Research stated in May 2006:

We highlighted in our 3Q 05 update report that pipeline drugs Exubera and Accomplia [sic] would positively impact Sanofi-Aventis' top-line growth in the coming 6-12 months. We had high expectations about the success of the drugs as both had huge market potential and were ranked amongst the top 10 potential blockbuster drugs to be launched in 2006 by Business Week, a leading business journal. We had anticipated the launch of these two drugs would help offset an expected decline in the company's revenues growth due to generic competition.

However, contrary to our expectations, Sanofi-Aventis entered into an agreement with Pfizer Inc. (Pfizer) in January 2006, to sell its share of the worldwide rights for Exubera for a cash consideration of US\$1.3bn. Although Sanofi-Aventis will receive the cash benefit, we are disappointed with the sale of the rights to this drug as we expected the drug to be a blockbuster and generate a significant and steady revenue stream over the years.

21. In September 2006, a Merrill Lynch equity analyst expressed the importance of rimonabant as a potential resolution to Sanofi's pipeline woes: “[b]eyond Acomplia, we see little in the way of positive catalysts. We remain concerned about the lack of late-stage pipeline progression in recent years.”

22. In December 2006, defendants held a conference call for analysts and investors to discuss the results of a recent rimonabant trial. During that call, defendants reassured the market of the safety of the compound:

- *“Overall, the safety profile was consistent with what we’ve seen in the past, which we found reassuring”;*
- *“And, again, consistent with the previously demonstrated safety profile, some increase in dizziness, nausea, which is usually mild, self-limited, normally one episode of slight nausea for example”;*
- *“And what we actually see, although, there is an increase in the frequency of depressed mood, **there is no increase in cases of depression.** And, in fact, there is a numerically smaller number of cases of depression **in rimonabant 20mg**, indicating that **whatever we’re seeing in this general area, seems to be mild and, perhaps, more of a tolerability issue than a safety issue**”;* and
- *“The fact that we see the imbalance in depressed mood and we don’t see it in depression just – it’s reassuring.”*

The RIO Studies: Unrevealed Adverse Side Effects and Study Defects Known by Defendants Prior to and During the Class Period

23. Between September 2001 and June 2004, Sanofi conducted the RIO Studies. RIO-North America and RIO Europe, completed around April 2004 and June 2004, respectively, were 2-year studies of the efficacy and tolerability of rimonabant, in conjunction with a reduced calorie diet, in obese and overweight patients with treated or untreated dyslipidemia (indicated by high levels of blood triglycerides or a high ratio of total cholesterol to “good” cholesterol, HDL), high-blood pressure or both. RIO-Diabetes, completed around May 2004, was a 1-year study in the same patient population with type-2 diabetes. RIO-Lipids, completed around November 2003, was a 1-year study of rimonabant in conjunction with a reduced calorie diet in obese and overweight patients with untreated dyslipidemia.

24. The safety data associated with the RIO Studies was grim. Based on the RIO Studies’ safety data, on February 17, 2006, the FDA sent Sanofi an approvable letter requesting that defendants submit supplemental data and analysis to address the agency’s concerns that use of rimonabant caused suicidality and depression. In fact, the supplemental data and analysis provided by defendants only confirmed the FDA’s concerns. The supplemental data from the RIO Studies

and other clinical trials completed by Sanofi, all of which were completed before the start of the Class Period, revealed 50 cases of suicidal ideation in rimonabant treatment groups compared to 14 in placebo – *nearly a tripling of the risk*. Moreover, while the RIO Studies excluded patients with a past history of severe depression or those who were currently on anti-depressant medication, a large number of patients with baseline histories of mood disorders and disturbances participated in the studies. Remarkably, 88% of those subjects (*i.e.*, 1082 out of 1235) in the rimonabant treatment groups who suffered adverse psychiatric events during the RIO Studies, such as depression, did *not* have a baseline history of mood disorders or disturbances. The incidence of all adverse psychiatric events in the RIO Studies was also double in the rimonabant treatment group, compared to placebo.

25. During a June 13, 2007 FDA Advisory Committee meeting, the adverse safety data was finally made public and Dr. Amy Egan, M.D., M.P.H., of the FDA's Division of Metabolism and Endocrinology Products ("DMEP"), concluded that this data established a causal connection between the use of rimonabant and depression and suicidal ideation.

26. The RIO Studies also identified serious safety signals with regard to the central nervous system ("CNS") and behavioral side effects. For instance, in the rimonabant treatment group, there was a six-fold increase in aggression compared to placebo. In addition, patients treated with rimonabant were twice as likely to suffer from memory loss or disorientation.

27. The RIO Studies were performed pursuant to the FDA's September 1996 Guidance for the Clinical Evaluation of Weight-Control Drugs ("1996 FDA Guidance"). The 1996 FDA Guidance required, as a condition to showing efficacy of a weight-control drug like rimonabant, that 1500 patients or more complete a 12-month trial. In contrast to the 1996 FDA Guidance, only approximately 1100 patients completed one year of treatment during the RIO Studies and defendants knew that this would dramatically decrease, if not eliminate, the possibility of FDA approval of

rimonabant for the treatment of obesity. Nonetheless, on March 9, 2005, defendant Cluzel responded to an analyst's question regarding the number of RIO Study patients who remained on rimonabant for one year, stating, ***"I'm sure it's more than 2,000."***

28. Defendants were also aware that the safety data of the RIO Studies would be subject to increased FDA scrutiny because of dramatic discontinuance rates by patients after suffering adverse events. The withdrawal rates during the first year of the RIO Studies ranged from 32% to 58% and, during the second year, 23% to 59% of the re-randomized patients withdrew. The RIO Studies' withdrawal rates only made the associated safety data regarding suicidality and depression more significant. As revealed during the June 13, 2007 FDA Advisory Committee meeting, Sanofi failed to conduct any systematic follow-up procedures with those individuals eliminated from the studies as a result of being placed on an anti-depressant after suffering an adverse psychiatric event. On March 9, 2005, however, defendants downplayed the significance of the drop-out rates and falsely assured investors that all patients who "discontinued for any reason" were followed up with in order to maintain the reliability of the studies' safety and tolerability data:

[T]he adverse events which are seen with [rimonabant] tend to occur early in treatment. Many of them are mild and transient. And those which lead to discontinuation do so in the early parts of treatment.

* * *

So patients who [were] discontinued for any reason or certainly for an adverse event were followed up. We have looked at . . . the profile of depression in the patients who were discontinued. And we find really no difference between the patients who were in the placebo group and the patients who were in active treatment in terms of the kinds of treatment that they had to receive, seriousness of depression, and so forth.

Defendants' failure to adopt systematic follow-up procedures with patients who were withdrawn as a result of being placed on anti-depressant medication served to manipulate the RIO Study data to show better levels of safety.

The Rimonabant Obesity NDA and Defendants' False and Misleading Statements

29. Months prior to March 1, 2005, defendants were fully aware of or recklessly disregarded the safety data in the RIO Studies that established a causal relationship between the use of rimonabant and psychiatric adverse events, including suicidality and depression. Nevertheless, defendants publicly discussed the purported high benefit/minimal risk profile of rimonabant as treatment for obesity, diabetes and cardiovascular ailments and submitted a NDA to the FDA for marketing approval of the drug for those indications. Defendants did not disclose to investors or the public the safety data which showed a causal connection between the use of rimonabant and serious side effects such as suicidality and depression.

30. Rather than disclose to investors the material information about suicidality and depression associated with rimonabant at the time Sanofi submitted its NDA in April 2005, and risk the sudden decline in the price of Sanofi's securities that would follow, defendants continued to disseminate false and misleading statements in press releases, SEC filings, conference calls and presentations to investors and the medical community. Defendants' Class Period statements reassured investors that rimonabant was effective and posed minimal risk, would fill the need of a massive market of individuals in the United States suffering from obesity, would fill gaps in the Company's deteriorating drug pipeline and would generate billions of dollars of revenue for Sanofi.

31. Throughout the Class Period, defendants informed investors that rimonabant would address the growing world epidemic of obesity – *“produc[ing] significant reductions and maintenance in waist circumference and weight improvements.”* In an April 11, 2005 press release, for example, defendants pitched rimonabant as *“the first in a new class of therapeutics called selective CB-1 receptor blockers . . . [the] [r]esults at two years from RIO Europe . . . have further confirmed the efficacy and safety of rimonabant in the long term.”* In addition, securities analysts following Sanofi repeated the defendants' false and misleading statements and omissions,

often emphasizing that “[rimonabant] is *en route to mega-blockbuster status*” as a result of “the lack of safe, tolerable and effective products for obesity,” and reiterated that the compound “*could be one of the most commercially successful drugs in history.*” In fact, in early June 2005, one analyst added €5.00 to his valuation of Sanofi based on defendant Dehecq’s confirmation that rimonabant sales forecasts of €3.2 billion in 2010 and €4.5 billion in 2015 were not excessive.

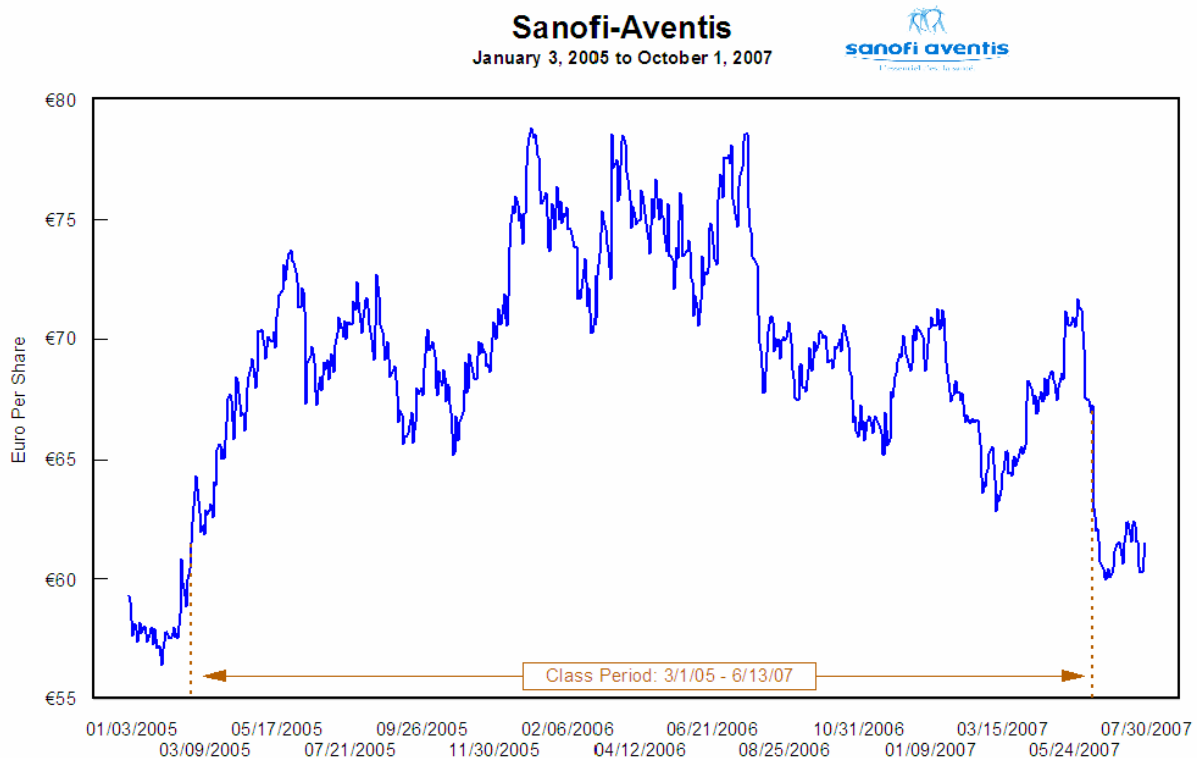
32. Without regard to the known safety issues associated with rimonabant, however, defendants continued to assure the market of the strength of Sanofi’s NDA filing with the FDA. Such statements included: “[w]e know that the products have been received, that they are of course fileable. And we are now starting to prepare the market”; “[w]e remain confident and prepared to launch [rimonabant] during the second half of 2005 – in 2006, excuse me”; and “we continue to plan for a launch also in the U.S. in the second half of 2006.”

33. Throughout the Class Period, defendants repeatedly reassured investors, the public and the medical community of the low-risk profile of the drug: “[t]he safety is, [one] more time, very good, and consistent with all we got in all the RIO Program [sic]”; “[s]ide effects were mainly mild and transient”; “[t]he most common [side effects] include[] nausea, dizziness, diarrhoea and vomiting”; “what we have observe[d] in depression (ph) is always minor”; “[o]n suicide [suicidality], in fact, we have no signal . . . [s]o no problem;” and “[t]he fact that we see the imbalance in depressed mood and we don’t see it in depression just – it’s reassuring.” On March 22, 2006, rather than disclose the truth about the causal link between rimonabant and suicidal ideation and depression, defendants proclaimed, “[y]ou know everything concerning rimonabant.”

34. In April 2007, a mere two months before the FDA Advisory Committee would make its recommendation on whether rimonabant should be approved to treat obesity in the United States,

defendants again assured the market that testing in Japan revealed “[r]imonabant demonstrated a good safety profile.”

35. Defendants’ Class Period statements were false and misleading and concealed the causal link between rimonabant and suicidal ideation and depression as discovered during the RIO Studies and other clinical trials conducted and sponsored by Sanofi. The following chart illustrates the artificial inflation of Sanofi’s common stock, as traded on the Paris Euronext, and its dramatic decline upon the disclosure of the safety issues associated with rimonabant and the FDA Advisory Committee’s unanimous vote that rimonabant should not be approved as a treatment for obesity in the United States.



The Truth is Uncovered and the FDA Advisory Committee Rejects Rimonabant

36. On June 13, 2007, defendants issued a press release stating that the FDA’s Endocrinologic and Metabolic Advisory Committee had, that day, rejected approval for rimonabant as a treatment for obesity in the United States. The committee’s recommendation was a resounding

14-0 vote against approval. As a result of the disclosures on June 13, 2007, Sanofi common stock trading on Euronext in Paris declined €4.26 and closed at €63.00 on June 14, 2007. Sanofi's American Depositary Shares ("ADSs") also dropped sharply on the NYSE on June 13 and June 14, 2007.

37. The June 13, 2007 Advisory Committee vote, for all intents and purposes, was a rejection of Sanofi's NDA for rimonabant as treatment of obesity in the United States and raised serious questions about the Company's ability to deliver revenue and profit growth in the future. On June 14, 2007, Max Herrmann of ING Wholesale Banking reported:

Acomplia: sales forecasts cut dramatically. We have reduced our risk-adjusted sales forecasts for [rimonabant] to €1.2bn in 2012F (previously €2.7bn) following an FDA advisory committee's unanimous vote not to recommend approval of the drug.

* * *

Since the advisory committee's recommendations are usually followed, ***the decision leaves almost no chance that [rimonabant] will be approved in the US in the near term.***

38. Also on June 14, 2007, Eric Le Berrigaud of Raymond James Euro Equities commented on the FDA Advisory Committee's vote and the threat it posed to Sanofi's drug pipeline:

The answer was a resounding "no", as the experts voted 14-0 against.

* * *

[T]he vote is likely to make a lot of noise in the press, both general and specialist.

* * *

We have decided to remove all sales contributions from rimonabant in the US (versus USD2.8bn in 2015 until now) and are reducing our estimates for Europe and elsewhere significantly. In all, we are cutting our peak sales estimate from EUR4.1bn to EUR800m in 2016.

* * *

Sanofi-Aventis is now in a sticky situation. Although it is important to secure mature products such as Lovenox and Plavix, ***the main question is whether the R&D pipeline will be able to deliver.***

39. In light of the disclosure of the safety issues and the Advisory Committee vote, on June 29, 2007, Sanofi completely withdrew its NDA for rimonabant, which means that the FDA will not meet to further consider approval of the drug.

THE PARTIES

Lead Plaintiffs

40. By Court Order dated February 29, 2008, the City of Edinburgh Council as Administering Authority of the Lothian Pension Fund (“Lothian Pension Fund”) and New England Carpenters Guaranteed Annuity Fund (“New England Carpenters Fund”) were appointed as Lead Plaintiffs in this action. The Lothian Pension Fund pays pensions to former employees of various city and regional councils, as well as other public sector organizations and is managed and administered in Edinburgh, United Kingdom. New England Carpenters Fund, managed and administered in Wilmington, Massachusetts, was established in 1981 and pays benefits to retired and disabled members. As set forth in the Certifications of the Lothian Pension Fund and New England Carpenters Fund, filed in connection with their motion to be appointed Lead Plaintiffs, they purchased Sanofi securities during the Class Period and, as a result of the defendants’ conduct detailed herein, suffered damages in connection with the purchase of Sanofi securities.

Defendants

41. Sanofi’s core business is the development and marketing of pharmaceuticals, with a focus on the therapeutic areas of thrombosis, cardiovascular, metabolic disorders, oncology, central nervous system and internal medicine. It is the third largest pharmaceutical company in the world. The Company was incorporated in France in 1994 as a *société anonyme* for a term of 99 years. In August 2004, Sanofi’s predecessor, Sanofi-Synthélabo, took control of Aventis and changed its

registered name to sanofi-aventis. In December 2004, the two companies merged and Sanofi was the surviving entity. Throughout the Class Period, Sanofi's ADSs traded on the NYSE and the Company's common stock traded on Euronext in Paris, France. In addition, Sanofi's depository shares and depository receipts traded on other exchanges around the globe.

42. Defendant Jean-François Dehecq ("Dehecq") served as CEO of Sanofi through December 31, 2006. At all relevant times, Dehecq was the Chairman of the Board of the Company. As part of his duties as Chairman and CEO, Dehecq was responsible for monitoring and reporting to investors and the market on the status of Sanofi's pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi's Code of Ethics, Dehecq was charged with determining whether to disclose information that would likely affect the Company's stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi's Code of Ethics required that Dehecq keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Dehecq participated in the issuance of false and misleading statements and failed to disclose that rimonabant caused depression and suicidal ideation as uncovered in the Company's clinical trials for the use of rimonabant for the treatment of obesity and other medical conditions. In addition to issuing statements throughout the Class Period, Dehecq repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) In conjunction with Sanofi's public financial statements filed with the SEC during the Class Period, Dehecq signed a certification pursuant to §302 of the Sarbanes-Oxley Act, attesting that he reviewed the contents of the filing to confirm the "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements

made, in light of the circumstances under which such statements were made, not misleading.” To assure that the certification was not simply a hollow gesture, Dehecq was required to and did further confirm that he, along with the Company’s Principal Financial Officer (“PFO”), was responsible for establishing and maintaining Sanofi’s disclosure controls and procedures, had designed such controls to assure that material information relating to Sanofi’s business was promptly made known to Dehecq and the Company’s senior executives and had routinely evaluated the effectiveness of the Company’s policies with regard to assuring that he and other executives were made aware of material information. At no time during the Class Period did Dehecq or any other defendant assert that they were not aware of material aspects of the status and results of Sanofi’s clinical trials and the NDA for the use of rimonabant as a treatment for obesity; and

(d) While CEO of Sanofi, Dehecq regularly visited the Company’s United States offices in Bridgewater, New Jersey, to conduct “town-hall” meetings during which he discussed current news, business and sales and Sanofi’s financial performance with United States employees. During the town-hall meetings, Dehecq personally presented information concerning rimonabant’s development and regulatory posture to Sanofi employees.

43. Defendant Gérard Le Fur (“Le Fur”) served as Senior Executive Vice President of Scientific and Medical Affairs until January 1, 2007, when he became CEO of the Company. As part of his duties at Sanofi, Le Fur was responsible for monitoring and reporting to investors and the market on the status of Sanofi’s pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi’s Code of Ethics, Le Fur was charged with determining whether to disclose information that would likely affect the Company’s stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi’s

Code of Ethics required that Le Fur keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Le Fur participated in the issuance of false and misleading statements and failed to disclose that rimonabant caused depression and suicidal ideation as uncovered in the Company's clinical trials for the use of rimonabant for the treatment of obesity and other medical conditions. In addition to issuing statements throughout the Class Period, Le Fur repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) In conjunction with Sanofi's public financial statements filed with the SEC during the Class Period, Le Fur signed a certification pursuant to §302 of the Sarbanes-Oxley Act, attesting that he reviewed the contents of the filing to confirm the "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading." To assure that the certification was not simply a hollow gesture, Le Fur was required to and did further confirm that he, along with the Company's PFO, was responsible for establishing and maintaining Sanofi's disclosure controls and procedures, had designed such controls to assure that material information relating to Sanofi's business was promptly made known to Le Fur and the Company's senior executives and had routinely evaluated the effectiveness of the Company's policies with regard to assuring that he and other executives were made aware of material information. At no time during the Class Period did Le Fur or any other defendant assert that they were not aware of material aspects of the status and results of Sanofi's clinical trials and the NDA for the use of rimonabant as a treatment for obesity;

(d) From March 1, 2005 through December 31, 2006, Le Fur reported directly to defendant Dehecq; and

(e) Throughout the Class Period, Le Fur regularly visited the Company's United States offices in Bridgewater, New Jersey, to conduct "town-hall" meetings during which he discussed current news, business and sales and Sanofi's financial performance with United States employees. During the town-hall meetings, Le Fur personally presented information concerning rimonabant's development and regulatory posture to Sanofi employees.

44. Defendant Jean Claude Leroy ("Leroy") was, at all relevant times, the PFO and Sanofi's Executive Vice President of Finance and Legal. As part of his duties as PFO, Leroy was responsible for monitoring and reporting to investors and the market on the status of Sanofi's pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi's Code of Ethics, Leroy was charged with determining whether to disclose information that would likely affect the Company's stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi's Code of Ethics required that Leroy keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Leroy participated in the issuance of false and misleading statements and failed to disclose that rimonabant caused depression and suicidal ideation as uncovered in the Company's clinical trials for the use of rimonabant for the treatment of obesity and other medical conditions. In addition to issuing statements throughout the Class Period, Leroy repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) In conjunction with Sanofi's public financial statements filed with the SEC during the Class Period, Leroy signed a certification pursuant to §302 of the Sarbanes-Oxley Act, attesting that he reviewed the contents of the filing to confirm the "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements

made, in light of the circumstances under which such statements were made, not misleading.” To assure that the certification was not simply a hollow gesture, Leroy was required to and did further confirm that he, along with the Company’s CEO, was responsible for establishing and maintaining Sanofi’s disclosure controls and procedures, had designed such controls to assure that material information relating to Sanofi’s business was promptly made known to Leroy and the Company’s senior executives and had routinely evaluated the effectiveness of the Company’s policies with regard to assuring that he and other executives were made aware of material information. At no time during the Class Period did Leroy or any other defendant assert that they were not aware of material aspects of the status and results of Sanofi’s clinical trials and the NDA for the use of rimonabant as a treatment for obesity;

(d) From March 1, 2005 through December 31, 2006, Leroy reported directly to defendant Dehecq and from January 1, 2007 through the end of the Class Period, Leroy reported directly to defendant Le Fur; and

(e) Throughout the Class Period, Leroy regularly visited the Company’s United States offices in Bridgewater, New Jersey, to conduct “town-hall” meetings during which he discussed current news, business and sales and Sanofi’s financial performance with United States employees. During the town-hall meetings, Leroy personally presented information concerning rimonabant’s development and regulatory posture to Sanofi employees.

45. Defendant Hanspeter Spek (“Spek”) was, at all relevant times, Executive Vice President of Pharmaceutical Operations. As part of his duties at Sanofi, Spek was responsible for monitoring and reporting to investors and the market on the status of Sanofi’s pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi's Code of Ethics, Spek was charged with determining whether to disclose information that would likely affect the Company's stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi's Code of Ethics required that Spek keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Spek participated in the issuance of false and misleading statements and failed to disclose that rimonabant caused depression and suicidal ideation as uncovered in the Company's clinical trials for the use of rimonabant for the treatment of obesity and other medical conditions. In addition to issuing statements throughout the Class Period, Spek repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) Between March 1, 2005 and December 31, 2005, Spek reported directly to defendant Dehecq, and thereafter directly to defendant Le Fur; and

(d) Throughout the Class Period, Spek regularly visited the Company's United States offices in Bridgewater, New Jersey, to conduct "town-hall" meetings during which he discussed current news, business and sales and Sanofi's financial performance with United States employees. During the town-hall meetings, Spek personally presented information concerning the rimonabant's development and regulatory posture to Sanofi employees.

46. Defendant Marc Cluzel ("Cluzel") was, at all relevant times, Senior Vice President of Development and Scientific Affairs. As part of his duties at Sanofi, Cluzel was responsible for monitoring and reporting to investors and the market on the status of Sanofi's pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi's Code of Ethics, Cluzel was charged with determining whether to disclose information that would likely affect the Company's

stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi's Code of Ethics required that Cluzel keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Cluzel participated in the issuance of false and misleading statements and failed to disclose that rimonabant caused depression and suicidal ideation as uncovered in the Company's clinical trials for the use of rimonabant for the treatment of obesity and other medical conditions. In addition to issuing statements throughout the Class Period, Cluzel repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) Between March 1, 2005 and December 31, 2005, Cluzel reported directly to defendant Dehecq, and thereafter directly to defendant Le Fur; and

(d) Throughout the Class Period, Cluzel regularly visited the Company's United States offices in Bridgewater, New Jersey, to conduct "town-hall" meetings during which he discussed current news, business and sales and Sanofi's financial performance with United States employees. During the town-hall meetings, Cluzel personally presented information concerning rimonabant's development and regulatory posture to Sanofi employees.

47. Defendant Douglas Greene ("Greene") was, at all relevant times, Vice President of Development and Scientific Affairs and Chief Medical Officer of Sanofi-U.S. Sanofi appointed defendant Greene to the position of Chief Medical Officer specifically to launch rimonabant in the United States because of his previous experience with drug and approval process with respect to other drug agencies around the globe. As part of his duties at Sanofi, Greene was responsible for monitoring and reporting to investors and the market on the status of Sanofi's pharmaceutical pipeline and new drug applications.

(a) During the Class Period, and pursuant to Sanofi's Code of Ethics, Greene was charged with determining whether to disclose information that would likely affect the Company's stock price, including the results of clinical trials relating to a strategic product. In addition, Sanofi's Code of Ethics required that Greene keep himself informed of all events that would likely affect the Company's stock price;

(b) During the Class Period, Greene participated in the issuance of false and misleading statements and failed to disclose that rimonabant caused depression and suicidal ideation as uncovered in the Company's clinical trials for the use of rimonabant for the treatment of obesity and other medical conditions. In addition to issuing statements throughout the Class Period, Greene repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Sanofi;

(c) Between March 1, 2005 and December 31, 2005, Greene reported directly to defendant Dehecq, and thereafter directly to defendant Le Fur; and

(d) Throughout the Class Period, Greene participated in "town-hall" meetings during which he discussed current news, business and sales and Sanofi's financial performance with United States employees. During the town-hall meetings, Greene personally presented information concerning rimonabant's development and regulatory posture to Sanofi employees.

JURISDICTION AND VENUE

48. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. §240.10b-5.

49. This Court has subject matter jurisdiction over the claims brought on behalf of United States-based investors who purchased or otherwise acquired Sanofi securities on the NYSE or any foreign exchange, and on behalf of all foreign purchasers who purchased or otherwise acquired Sanofi securities on the NYSE because:

(a) Defendants' wrongful conduct alleged herein had a substantial effect upon the United States markets, United States-based and foreign investors and the price of Sanofi's securities on the NYSE and foreign exchanges;

(b) Defendants' activities in the United States were more than merely preparatory to securities fraud conducted elsewhere and their activities or culpable failures to act within the United States directly caused plaintiffs' losses;

(c) The Company's ADSs trade on the NYSE and the Company files regular, periodic financial reports with and is subject to the jurisdiction of the SEC and, thus, the United States federal securities laws;

(d) Sanofi maintains a significant presence in the United States, which is a critical component of the Company's global business. Like many of Sanofi's drugs, the Company sought approval of rimonabant with the FDA so the drug could be marketed for various indications within the United States. The Company has thousands of employees throughout the United States. Sanofi retains sales force regional offices in the states of New York, Pennsylvania, Missouri, Atlanta, Texas and California. Sanofi maintains its United States central drug distribution facility in Des Plaines, Illinois. The Company also maintains a drug manufacturing facility in Missouri as well as training facilities in New York;

(e) The defendants utilized the United States mails, interstate wires and the facilities of the United States securities exchange in furtherance of the fraud alleged herein. Prior to and during the Class Period, Sanofi conducted numerous conference calls with analysts located in the United States. Defendants Dehecq, Le Fur, Spek, Leroy and Cluzel conducted conference calls in the United States (including in New York City) and met in person with analysts and investors located in the United States. Furthermore, during the Class Period, the individual defendants knew

they were disseminating materially misleading information concerning the Company's results of operations to shareholders residing throughout the United States; and

(f) The defendants have extensive contact with the United States regulatory agencies, such as the FDA and the United States Patent and Trademark Office regarding the promotion, manufacturing and patenting of their pharmaceutical products within the United States, including the ill-fated rimonabant.

50. This Court may exercise personal jurisdiction over each individual defendant because each has availed himself of the privileges and protection of the laws of the United States and its several states, and this litigation arises out of each individual defendants' contacts with the United States. The individual defendants caused Sanofi to litigate patent cases in federal courthouses throughout the United States to protect the Company's revenue streams from generic competition. In fact, in August 2006, the individual defendants caused Sanofi to seek a preliminary injunction in this very district, which the court granted, in order to stop the sales of generic Plavix. During the Class Period, the individual defendants regularly traveled to various locations within the United States on Sanofi business. Defendants Dehecq, Le Fur, Spek and Leroy were present in New York City during the Class Period for the purpose of participating in an analyst and investor conference. The individual defendants signed quarterly or annual reports on Forms 6-K and 20-F, which were filed with the SEC and contained alleged misrepresentations and/or omissions and each individual defendant caused the dissemination of false and misleading reports and statements to Sanofi investors in the United States. Each individual defendant knew that Sanofi's securities traded in the United States. Each individual defendant knew that the Company's press releases were disseminated in the United States, that the Company regularly filed reports with the SEC and that United States investors would rely upon the information contained in the reports and releases. Each individual

defendant engaged in a course of unlawful conduct that had an effect in the United States, regardless of where such conduct occurred, by influencing United States investors and foreign investors who invested in Sanofi securities traded in the United States. These United States-based effects were both the direct and foreseeable results of the individual defendants' unlawful conduct as alleged herein.

51. Venue is proper in this district pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b). Many of the acts and transactions giving rise to the violations of law complained herein occurred in substantial part in this district. Sanofi's ADSs trade on the NYSE, which is located in this district, and the Company markets and sells its pharmaceutical products within this district.

PRE-CLASS PERIOD EVENTS AND DEFENDANTS' KNOWLEDGE OF THE RIO STUDIES' SAFETY DATA

52. On November 9, 2004, Dr. F. Xavier Pi-Sunyer, the principal investigator for Sanofi's RIO-North American Phase III study, stated, “[t]here was *no evidence that this drug in two years had something we have to worry about in regard to safety*.” To the contrary, the safety data associated with the RIO Studies – in particular, the undisclosed data as it related to suicidality and depression – portrayed a markedly different story.

53. All four RIO Studies were completed by June 2004, well prior to the start of the Class Period. Not only did the individual defendants receive the efficacy/safety results of each clinical trial conducted/sponsored by Sanofi shortly after it was completed, but the individual defendants, as members of Sanofi's senior management, had access to the Company's clinical trial database – “ClinTrial” – which contained all data used in communicating efficacy/safety data to the FDA and European Medicines Agency (“EMA”). Not only did the individual defendants receive the Study Report for each of the RIO Studies well in advance of the beginning of the Class Period, but the

individual defendants knew of the existence of ClinTrial and had direct access to its contents *via* Sanofi's computer network.

Defendants' Knowledge/Access to the Contents of Study Reports and ClinTrial

54. Throughout the Class Period, the individual defendants held themselves out to investors and the market as the persons most knowledgeable at Sanofi about the Company's drug pipeline, NDA submissions and safety data associated with Sanofi clinical trials. As described more fully in ¶¶42-47, each of the individual defendants held one of the most senior positions at Sanofi with responsibility for deciding what information concerning the Company's drugs should be disclosed to investors and, in accordance with Sanofi's Code of Ethics, were charged with keeping themselves informed of information concerning Sanofi's drugs that may affect the price of the Company's securities.

55. During the Class Period, the individual defendants specifically and repeatedly touted the safety profile of rimonabant, purportedly based on their access to, and knowledge of, safety data contained in Sanofi's computer network and Study Reports that detailed the efficacy and safety results of each of the RIO Studies. On March 9, 2005, defendants informed the market that "*we have looked at the database fairly closely and no concerns have arisen . . . [W]e're well along in amassing the entire [safety] database.*" In addition, the individual defendants reassured investors on March 22, 2006, based on their access to the Company's safety database and RIO Study Reports, that they disclosed all material information concerning their wonder-drug: "*[y]ou know everything concerning rimonabant.*"

56. The defendants routinely communicated with analysts and investors during the Class Period and represented that they were informed of and knowledgeable about rimonabant's efficacy, safety profile and the compound's travels throughout the FDA approval process. ¶¶66-70, 74-75, 79-80, 83, 85-93, 95-96, 99-104, 106, 109-112, 114-115, 118-119, 121-122. In the course of these

communications, defendants presented detailed information regarding the drug. ¶¶66-70, 74, 79-80, 87, 90, 93, 95-96, 99-103, 106, 109-112, 114-115, 119, 112. As detailed below, such information was available to the individual defendants, for purposes of presentation to analysts and investors, *vis-à-vis* their direct access to Sanofi's clinical trial safety database and possession of clinical trial Study Reports. Accordingly, defendants represented to the market that they had intimate knowledge of these areas and responded to questions focused on the drug's efficacy, safety profile and the FDA regulatory process. At no time did any of the individual defendants respond that they were uninformed, or did not have access to, material information concerning rimonabant.

57. In addition, prior to and during the Class Period, Sanofi had in place policies and procedures for the communication of study results to senior management, including each of the individual defendants. A Study Team was assigned to each Sanofi rimonabant clinical trial, including the RIO Studies. The Study Teams were part of Sanofi's Clinical Operations Department. The Study Teams consisted of: (a) a Study Manager and Project Lead who were responsible for the conduct, progress and outcome of the study; (b) a Data Manager who was responsible for handling, reviewing and maintaining all study data; (c) a Lead Clinical Research Associate who was responsible for monitoring clinical trial sites; (d) a Statistician who was responsible for analyzing final study results and preparing Study Reports; and (e) a Medical Officer who was responsible for monitoring various medical issues associated with the particular study.

58. As each study participant experienced an adverse event, Sanofi was required to create a Case Report Form ("CRF"), which contained details regarding the particular adverse event reported by a patient. The study Data Manager was responsible for entering the CRF data into the Company's database – ClinTrial. Upon completion of each clinical study, the Data Manager was responsible for locking the contents of the study efficacy and safety results into ClinTrial.

59. Once the study data had been locked into ClinTrial, the data was in a format that allowed the Statistician assigned to the study to begin statistical analysis. The Statistician analyzed the data, prepared graphs and the Study Report itself (which contained the clinical study results) in accordance to the Statistical Analysis Plan prepared by the same Statistician in the planning phase of the study. It was a relatively quick process to prepare a Study Report at Sanofi after the Statistician obtained access to the data in ClinTrial. At Sanofi, the Statistician generally completed the RIO Study Reports within two to six weeks of completion of each study.

60. After the Statistician completed the Study Report, it would be submitted to one of Sanofi's Head Physicians in the Clinical Operations Department. The Head Physician reviewed the Study Report for the purpose of determining whether the report was positive (*i.e.*, more effective than placebo) or negative (*i.e.*, not more effective than placebo), overall safety results and whether there were any unusual or unexpected adverse events. After completing the review of each of the RIO Study Reports, the reports would be provided to the Chief Medical Officer, Greene, and the rest of senior management, including the other individual defendants.

Defendants' Role With Regard to FDA Approval Process of Rimonabant – Post February 17, 2006

61. On February 17, 2006, defendants disclosed only the receipt of the FDA approvable letter. In fact, its contents cast grave doubts regarding the agency's approval of rimonabant. The letter revealed that the agency and, in particular, the DMEP, withheld approval of rimonabant as a treatment for obesity based on the RIO Studies' signaling of serious safety issues, including suicidality and other psychiatric adverse events. An FDA briefing document authored in connection with the June 13, 2007 Advisory Committee specifically describes the contents of the approvable letter:

[The DMEP's] [r]eview of the preclinical and clinical data raised concern about associations between rimonabant and increased frequencies of psychiatric

adverse events, including suicidality ***Based on these concerns DMEP sent Sanofi-Aventis an approvable letter in February 2006, requesting that they provide additional data and analyses to more precisely characterize these potential drug-related adverse events.***

These additional data and analyses [were] submitted by Sanofi-Aventis in October 2006.

62. The individual defendants directly participated in the efforts necessary to obtain approval for rimonabant after receipt of the FDA's February 17, 2006 letter. During the Class Period, defendants admitted that they were working closely with the FDA and they were maintaining an ongoing dialogue with the agency concerning the drug's potential approval. Moreover, the individual defendants participated in regular meetings to discuss the FDA approval process after February 17, 2006. In connection with those meetings, the individual defendants received an Executive Summary, which contained minutes of prior meetings (*e.g.*, emails detailing agendas, participants and topics of discussion), and a status of the FDA's position, guidance and requests for additional safety data concerning rimonabant.

63. Moreover, defendants were motivated to conceal the causal connection between rimonabant and suicidal ideation and depression during the Class Period in order to avoid increased scrutiny of outstanding drug applications by regulatory bodies other than the FDA. When Sanofi received the FDA letter in February 2006, it then had new drug applications for rimonabant as an obesity treatment outstanding with the European Commission, Mexico, Switzerland and Brazil. These applications were set to be, and were, acted on before the FDA Advisory Committee had a chance to address the rimonabant safety data. Had defendants disclosed on February 17, 2006 that the FDA had requested additional data and analysis from Sanofi to address the agency's concern about associations between rimonabant and suicidality and psychiatric adverse events, defendants knew that the Company's outstanding drug applications would have been placed in jeopardy.

64. As a spokesperson for the EMEA noted shortly after the FDA Advisory Committee's June 13, 2007 vote on rimonabant, "if a big regulatory authority takes a decision or if such information comes to light then these things come on to the [EMEA's] agenda." Thereafter, on July 19, 2007, the EMEA's Committee for Medicinal Products for Human Use recommended that rimonabant be banned for use in patients with ongoing major depression and patients taking antidepressants. It also recommended that the product's labeling include a warning that should patients taking the drug begin suffering from depression, they should immediately stop treatment.

65. Defendants also knew that if other regulatory agencies discovered the FDA's concerns as expressed in the February 2006 letter, reimbursement by insurance companies and governments for use of the drug as obesity treatments would have been at risk. As a non-reimbursable drug, sales of rimonabant would be markedly lower than if reimbursed by state sponsored health plans or insurance companies. Indeed, after the February 2006 letter, but before the disclosures of June 13, 2007, the governments of Sweden and France classified rimonabant as reimbursable by the state.

DEFENDANTS' FALSE AND MISLEADING CLASS PERIOD STATEMENTS

False and Misleading Statements Made Between March 1, 2005 and June 24, 2005

66. The Class Period commences on March 1, 2005. On that day, defendants hosted Sanofi's fiscal year 2004 earnings conference call for investors and analysts, during which defendants Dehecq, Spek, Leroy and Le Fur were present. Defendants discussed, *inter alia*, the results of a STRATUS study (rimonabant as a smoking cessation treatment) and the pending release of the RIO-Europe study results. Le Fur noted with regard to the STRATUS results: "***The safety is, [one] more time, very good, and consistent with all we got in all the RIO program [sic].***" In closing his remarks, Le Fur positioned rimonabant was a "potential blockbuster."

67. On March 8, 2005, Sanofi arranged for the publication of a press release by Luc Van Gaal, M.D., the principal investigator of the RIO-Europe Study. As the sponsor of RIO-Europe, Sanofi compensated Van Gaal for his oversight of the study. Not only did Van Gaal hype the effectiveness of rimonabant as a treatment for obesity, but he downplayed its side effects:

Side effects were mainly mild and transient and appeared mainly in the first year. The most common [side effects] included nausea, dizziness, diarrhoea and vomiting. Overall discontinuation rates due to adverse events in the two years of the study were 13.1[%], 10.9[%] and 18.9[%] in the placebo, rimonabant in 5[mg/day] and rimonabant 20 mg/day groups, respectively.

68. On March 9, 2005, defendants held a conference call for investors and analysts, during which defendants Cluzel and Greene were present. During the call, they presented the results of the recently completed RIO-Europe Study:

[GREENE] *Rimonabant produces significant reductions and maintenance in waist circumference and weight improvements; significant improvements in metabolic profile with increased HDL and reduced triglycerides; increased insulin sensitivity; and an absolute maintenance of the, I think, very important decrease in the prevalence of subjects with metabolic syndrome, which was seen at 1 year, is carried through into the second year without any suggestion of loss of effect. About half of the metabolic effects were independent of body weight, and reflect the unique pharmacology of Rimonabant. And so the effects that are achieved at 1 year are maintained in the second year – a good 1- and 2-year safety profile, and a safety profile which, in the second year, is essentially identical or comparable to what we see in the placebo group.*

* * *

At the present time, we have – no concern has come out of the [safety] data in terms of other, as you would call them, unusual CNS side effects. *I think at this point, we have looked at the database fairly closely and no concerns have arisen. And as you know, we're well along in amassing the entire [safety] database.*

* * *

[CLUZEL] *Anyway, what we have observe in depression (ph) is always minor.*

* * *

We have a small signal in CNS, but it is partly mixed with the activity of the drugs. And anyway, it is mild and it is transient.

* * *

On suicide [suicidality], in fact, we have no signal. And if we have one signal, it is in placebo. *So, no problem.*

* * *

[GREENE] *Yes . . . patients who are discontinued for any reason or certainly for an adverse event were followed up. We have looked at the – I guess, the profile of depression in the patients who were discontinued.* And we find really no difference between the patients who were in the placebo group and the patients who were in active treatment in terms of the kinds of treatment that they had to receive, seriousness of depression, and so forth.

69. During the March 9, 2005 conference call, in response to an analyst's question concerning the number of patients who had completed 12 months on a 20 mg regimen of rimonabant, defendant Cluzel responded, *"I'm sure it's more than 2,000."*

70. On April 11, 2005, Sanofi filed with the SEC its Form 20-F for the fiscal year ended December 31, 2004. Sanofi's Form 20-F, signed by defendant Dehecq, contained the following statements about rimonabant:

Rimonabant is the first in a new class of therapeutics called selective CB-1 receptor blockers. CB-1 receptors were found first in the brain and identified now in several human tissues They are part of the endocannabinoid system, which is critically involved in the regulation of body mass and body weight, lipid metabolism and insulin resistance.

* * *

Results at two years from RIO North America demonstrated statistically significant weight loss and decrease of waist circumference while providing improvement of metabolic parameters over the second year compared to patients switching treatment to placebo at the end of the first year. ***The results at two years from RIO Europe, presented at the American College of Cardiology in March 2005 have further confirmed the efficacy and safety of rimonabant in the long term*** together with an improvement in cardiovascular risk factors demonstrated over the second year.

71. Filed together with Sanofi's Form 20-F were certifications from defendants Dehecq and Leroy in compliance with §§302 and 906 of the Sarbanes-Oxley Act of 2002. Included in the

certifications were statements by Dehecq and Leroy asserting that they had reviewed Sanofi's Form 20-F and that the public "report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading."

72. On June 2, 2005, defendant Dehecq participated in the annual European Federation of Pharmaceutical Industries and Association meeting. On that day, Dehecq informed the market that rimonabant sales of €3.2 billion in 2010 and €4.5 billion in 2015 were not excessive forecasts.

73. The following day Florent Caspedes of Natexis Bleichroeder, an equity analyst covering Sanofi, reported that Dehecq's remarks led to a €5 per share increase in the analyst's valuation model and Dehecq's statements "should have a positive impact on [Sanofi's] shares."

74. On June 13, 2005, defendants held a conference call for investors and analysts, during which defendants Cluzel and Greene participated. The conference call was held to announce the results of RIO-Diabetes the last of the four RIO Studies. Greene presented in San Diego, California, and Cluzel presented from Paris, France.

[GREENE] The next slide, number 23, is designed to reinforce the consistency of effect across the entire scope of what we would see as a metabolic target population covered in the 4 RIO studies, with consistent improvements in the 4 major components of the metabolic syndrome, waist circumference, HDL-cholesterol, triglyceride.

* * *

The adverse events are listed on slide 25. The ones which occur with greater than 5% frequency, and again we see nausea, we see some dizziness which is almost all of that is transient and mild. . . . [O]ne episode of nausea, one episode of dizziness. Vomiting is again shows [up to as it has been before], usually is a, again, transient self-limited.

* * *

[MICHAEL LEACOCK – Nomura Securities] On the safety issue, you mention an 8% of patients with a serious adverse event. Could you just talk a little bit about what those adverse events were?

* * *

[GREENE] With regard to your question about serious adverse events, generally the SAEs were widely scattered. ***I don't have those figures in front of me at the moment.*** They were widely scattered and essentially were exactly what you would expect in a patient population at high risk type 2 diabetes. ***I don't have the full list of SAEs, but they were mostly disease related.***

75. On June 23, 2005, the Company announced that the FDA had accepted Sanofi's April 2005 NDA submission of rimonabant as an indication for the treatment of obesity. The press release was also filed with the SEC as an exhibit to Sanofi's Form 6-K on June 24, 2005. In its press release, the Company stated that rimonabant was "thought to represent a new approach for the comprehensive management of cardiovascular risk factors," including obesity.

76. Defendants' statements made between March 1, 2005 and June 24, 2005 were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of the RIO Studies, which showed a causal link between the use of rimonabant and depression. In fact, out of 1,253 psychiatric adverse events reported, which included various degrees of severity of depression, 1082 (88%) of them were suffered by patients in the rimonabant treatment group who did not have a baseline history of mood disorders;

(b) Prior to and during the Class Period, defendants were in possession of the efficacy and safety results of at least 12 rimonabant clinical studies, including the RIO Studies, which showed a causal link between rimonabant and suicidal ideation. In fact, the studies revealed 50 cases of suicidal ideation were associated with use of rimonabant, while only 14 were associated with placebo; and

(c) During the RIO Studies, withdrawal rates for the RIO Studies ranged from 32% to 49% for the first year and 23% to 58% for the second year. Defendants failed to implement

systematic follow-up procedures with patients who withdrew as a result of suffering an adverse psychiatric event, or with those patients that were excluded from the study by Sanofi because they went on a regimen of anti-depressants while a study was ongoing. As a result, defendants were unable to determine how long patients remained depressed and whether the severity of depression increased or decreased after withdrawal or exclusion from the study.

77. As a result of defendants' false statements and omissions between March 1, 2005 and June 24, 2005, Sanofi's stock traded at artificially inflated levels. During that period, defendants' misleading statements and omissions of material information about rimonabant had a direct effect on Sanofi's stock price, which increased €7.45 per share.

False and Misleading Statements Made Between August 31, 2005 and February 14, 2006

78. On August 31, 2005, defendants held a conference call for investors and analysts, during which defendants Leroy, Dehecq, Spek and Le Fur were present. During the call, defendants addressed rimonabant and the Company's recent FDA submission. Defendant Spek stated:

You see this Company today has seven . . . blockbusters.

* * *

Now we have everything in place to enlarge this list, through Rimonabant, Acomplia. We have once again delivered what we promised. [Le Fur] has deposited with his people the files with EMEA and FDA exactly on time. We know that the products have been received, that they are of course fileable. And we are now starting to prepare the market.

79. On September 23, 2005, Sanofi issued its Interim Report for the six months ended June 30, 2005. The Interim Report was filed with the SEC as an exhibit to Sanofi's Form 6-K on September 23, 2005. The Interim Report stated:

Highlights of the first half of 2005 for the pharmaceutical business:

* * *

[T]he first-year results of the **RIO-Europe** (Rimonabant In Obesity – Europe) study were published The report concluded that rimonabant held therapeutic promise in improving several cardiovascular and metabolic risk factors.

* * *

[T]he results were announced of the **RIO-Diabetes** phase III clinical trial on **rimonabant**, which demonstrated significantly improved [blood sugar control] and cardiometabolic risk factors in patients with type 2 diabetes. New drug applications were filed for rimonabant in the United States and Europe during the second quarter of 2005.

80. On February 14, 2006, Sanofi issued a press release entitled “The Journal of the American Medical Association publishes the RIO-North America Study,” which stated:

Study Shows Rimonabant Maintains Improvements in Multiple Cardiometabolic Risk Factors For Up to Two Years

Sanofi-aventis announced that the results of the RIO-North America trial were published today in The Journal of the American Medical Association (JAMA). The trial evaluated two-year treatment with rimonabant in overweight or obese patients, many of whom were at increased risk for diabetes and heart disease through the presence of additional risk factors including increased waist circumference (abdominal obesity), elevated blood pressure or abnormal lipid levels. The findings showed that patients treated with rimonabant 20 mg once daily experienced significant reduction of their waist circumference and body weight as well as improvements in multiple cardiometabolic risk factors, including HDL (good) cholesterol, triglycerides and an estimate of insulin sensitivity.

“The RIO-North America trial results indicate that rimonabant 20 mg once daily produced sustained clinically meaningful weight loss and improvements in associated risk factors during two years of treatment,” said Xavier Pi-Sunyer, M.D., Chief of the Division of Endocrinology, Saint Luke’s – Roosevelt Hospital Center, Columbia University, New York, Professor of Medicine at Columbia University College of Physicians and Surgeons; and Principal Investigator of the RIO-North America trial. ***“The sustained improvements we see in several risk factors were beyond what was expected from the observed weight loss and suggests that rimonabant represents an exciting breakthrough in our quest to improve the multiple cardiometabolic risk factors contributing to increased risk for diabetes and heart disease in patients who have abdominal obesity.”***

* * *

Importantly, the RIO-North America trial results suggest that patients taking rimonabant 20 mg once daily maintained their weight loss during the second year of

treatment and continued to experience favorable improvements across multiple cardiometabolic risk factors.

* * *

Safety and tolerability were consistent with other reported RIO studies. In the first year, rimonabant 20 mg once daily was generally well-tolerated and adverse events were mostly mild to moderate. The most common side effects for the placebo and rimonabant 20 mg arms included upper respiratory tract infection (15.2 % vs. 18.5 %), nasopharyngitis (14.0 % vs. 17.0 %), nausea (5.8 % vs. 11.2 %), influenza (7.7 % vs. 8.8 %), anxiety (2.1 % vs. 6.1 %), and depressed mood (3.1 % vs. 5.2 %). Overall, discontinuation rates due to adverse events in the first year of the trial were 7.2 % in placebo treated patients vs. 12.8 % for rimonabant 20 mg patients. The most common adverse events leading to discontinuation for the placebo and rimonabant 20 mg patients respectively were depressed mood disorder (1.3 % vs. 2.2 %), anxiety (0.3 % vs. 1.0 %) and nausea (0.2 % vs. 0.9 %).

In the second year, overall rates of adverse events, discontinuations and adverse event-related discontinuations were lower than in the first year, with no significant differences between rimonabant 20 mg and placebo.

81. Defendants' statements made between August 31, 2005 and February 14, 2006 were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of the RIO Studies, which showed a causal link between the use of rimonabant and depression. In fact, out of 1,253 psychiatric adverse events reported, which included various degrees of severity of depression, 1082 (88%) of them were suffered by patients in the rimonabant treatment group who did not have a baseline history of mood disorders;

(b) Prior to and during the Class Period, defendants were in possession of the efficacy and safety results of at least 12 rimonabant clinical studies, including the RIO Studies, which showed a causal link between rimonabant and suicidal ideation. In fact, the studies revealed 50 cases of suicidal ideation were associated with use of rimonabant, while only 14 were associated with placebo; and

(c) During the RIO Studies, withdrawal rates for the RIO Studies ranged from 32% to 49% for the first year and 23% to 58% for the second year. Defendants failed to implement systematic follow-up procedures with patients who withdrew as a result of suffering an adverse psychiatric event, or with those patients that were excluded from the study by Sanofi because they went on a regimen of anti-depressants while a study was ongoing. As a result, defendants were unable to determine how long patients remained depressed and whether the severity of depression increased or decreased after withdrawal or exclusion from the study.

82. As a result of defendants' false statements and omissions between August 31, 2005 and February 14, 2006, Sanofi's stock traded at artificially inflated levels. During that period, defendants' misleading statements and omissions of material information about rimonabant had a direct effect on Sanofi's stock price, which increased €3.35 per share.

False and Misleading Statements Made Between February 17, 2006 and May 5, 2006

83. On February 17, 2006, Sanofi issued a press release announcing that the Company received an approvable letter from the FDA for rimonabant for the treatment of obesity. The press release was also filed with the SEC as an exhibit to Sanofi's Form 6-K on February 21, 2006. The press release stated:

Sanofi-aventis announced today that it has received from the U.S. Food and Drug Administration (FDA), Division of Metabolism and Endocrinology Products an approvable letter for rimonabant for weight management, and from the Division of Anesthesia, Analgesia and Rheumatology Products a non approvable letter for smoking cessation.

Sanofi-aventis will continue to work in close collaboration with the FDA.

84. After announcing this news, Sanofi's stock price dropped approximately €2.20 by the close of trading on February 20, 2006. Defendants continued their crusade of informing investors that the Company would continue to cooperate with the FDA in order to launch rimonabant in the

United States by the end of 2006 and continued to pitch the purported high-benefit/low risk profile of the Company's magic bullet drug.

85. As subsequently reported by the *Wall Street Journal*:

IN THE EARLY EVENING of Friday, Feb. 17, French pharmaceuticals giant Sanofi-Aventis SA said it had received from the [FDA] a letter saying the regulator would approve Sanofi's weight-loss drug only if the company could meet certain conditions.

[On February 19, 2007] Sanofi's investor-relations department took calls from research analysts who follow the company closely. The company officials passed on a crucial piece of intelligence about the drug's future prospects [*i.e.*, that Sanofi expected the FDA to approve rimonabant by the second half of 2006].

* * *

Sanofi's shares fell 3.1% that Monday, to 71.70 Euros (\$84.95) – a significant drop, but not as much as they might have fallen had the company not reassured some investors about its most important new drug.

86. On February 24, 2006, defendants held a fourth quarter 2005 earnings conference call for investors and analysts, during which defendants Dehecq, Le Fur, Leroy and Spek were present. During the conference call defendants made a presentation to analysts and investors that emphasized the enormous market potential for rimonabant in the United States ("100 [million] Americans . . . are considered to suffer from abdominal obesity") and demonstrated how the drug would help millions of patients suffering from multiple cardio-metabolic risk factors associated with abdominal obesity, such as glucose intolerance, insulin resistance, intra abdominal adiposity and dyslipidaemia. During their presentation defendants confirmed that the RIO Studies supported rimonabant's effectiveness in the management of these cardio-metabolic risk factors and a third quarter or fourth quarter 2006 launch date for the drug in the United States.

87. During the February 24, 2006 conference call, Pierre Chancel, Sanofi's Senior Vice President of Global Marketing for the Pharmaceuticals, in the presence of defendants Dehecq, Le Fur, Leroy and Spek, discussed rimonabant in connection with the slide presentation, stating:

First of all let me start in framing the scope of what we are talking about when we speak about cardiometabolic risk, abdominal obesity and related commodities.

* * *

Then last, let me call or let me talk about Rimonabant now, and I will summarize the RIO program and in the RIO program is four studies, RIO Europe, RIO North America, lipid and diabetes. And this program involves almost 7,000 patients. And the beauty of these trials showed that, first of all a great result that I will comment, and the second thing is a very consistent data across the four studies.

* * *

Now, let's think a little bit about the future because we got some great data on the RIO program. So the reason why we wanted to have a complete and very comprehensive lifecycle management program that could enable us to leverage this product or the data for the full benefit of the patient in all the components of the cardiometabolic's risk.

* * *

Now, this is what we have done and what we do in terms of activity, but let's speak or start to speak a little bit about the outcome. And, regarding the outcome, it's about Rimonabant awareness in the U.S., so this is a U.S. database, amongst GPs, cardiologists and endocrinologists, and you can see a massive improvement between 2004 and 2005 in terms of Rimonabant awareness.

* * *

The second point is that we have a fantastic product with Rimonabant, that for the first time and I insist for the first time, was able to demonstrate a unique mode of action, so a unique benefit in being able to address multiple cardiometabolic risks factors with one single agent.

And, I would say last but not least, it's about our ambition, ambition to deliver and do the best for, not only the product but, obviously, for the patient, because we are convinced that this product, if we put the right level of energy at the physician level, at the patient level and at the payer level, we'll be able to change and re-define the way cardiometabolic risk will be managed.

88. During the February 24, 2006 conference call defendant Le Fur discussed the February 17, 2006 FDA letter regarding rimonabant, stating:

So as you know, in the non-approvable letter that we received on Rimonabant, the FDA asked us to perform an additional clinical study in smoking

cessation. ***But in the approvable letter, no additional trial in obesity has been requested by the agency and we will meet the FDA in the coming weeks to address all remaining issues.***

89. During the February 24, 2006 conference call, analysts from Prudential Securities, Merrill Lynch and ABN Amro and *The Wall Street Journal* sought more information from defendants about rimonabant. For instance:

[PRUDENTIAL SECURITIES ANALYST] Okay, and just how about that other question about when we're going to learn more about your meeting with FDA?

[LE FUR] No, no. First of all, we have to meet them and we don't want to say anything about that. ***Please understand that our first priority is to meet them and to work on the dossier and not to communicate on that.***

90. On March 22, 2006, defendants held a fiscal year 2005 conference call for analysts and investors in New York, during which defendants Dehecq, Le Fur, Spek and Leroy were present. During the conference call, defendants made a presentation to analysts and investors that repeated the presentation made during the February 24, 2006 conference call, emphasizing the large market for rimonabant in the United States and how the drug would help millions of patients suffering from multiple cardio-metabolic risk factors associated with obesity. During their presentation defendants discussed the RIO Studies and stated that the studies supported rimonabant's effectiveness in the management of cardio-metabolic risk factors. Defendants also confirmed a 2006 launch date in the United States. During the conference call, defendant Spek stated:

From this chart, the take away – the most important one is that we have proof that concerning the four major cardio-metabolic risk factors, rimonabant has a direct effect on three [instances] independent of weight reduction. ***And this really gives the true magnitude to this product.***

91. During the March 22, 2006 conference call, an unidentified Sanofi representative added:

[COMPANY REPRESENTATIVE] ***You know everything concerning rimonabant.*** I can just add that we are currently working with the FDA concerning rimonabant,

but I'm sorry to say that but you're pretty sure of what I said that will not comment anymore about rimonabant.

92. During the March 22, 2006 conference call, an analyst from Prudential Securities, again sought more information from defendants about rimonabant:

[PRUDENTIAL SECURITIES ANALYST] Two questions. Maybe one for [Le Fur]. I know you said you are not going to give an update on the Acomplia yet. But you had the meeting with the FDA I'm just wondering what the form for the next update is going to be, is it an earnings call most likely? Or at what point in the future – are we looking at weeks, months, or quarters, something like that?

[LE FUR] I'm really sorry. As I mentioned to you, ***we will not comment anymore on rimonabant*** and what we are currently doing with the FDA. Sorry for this.

[COMPANY REPRESENTATIVE] I'm sorry. I will repeat. I'm really sorry, but I'm pretty sure that you can understand that [we] will not comment anymore on rimonabant and what we are currently doing with the FDA.

93. On March 31, 2006, Sanofi filed with the SEC its Form 20-F for the fiscal year ended December 31, 2005. Sanofi's Form 20-F, signed by defendant Dehecq, contained the following statements about rimonabant:

In 2005, the first full calendar year for sanofi-aventis, our large R&D organization was integrated and, on top of smooth progress for the projects in our portfolio, achieved significant goals with two major submissions in the United States and Europe (rimonabant and dronedarone).

* * *

Rimonabant has completed a phase III program in obesity, cardiometabolic risk management and related disorders like type 2 diabetes and dyslipidemia (the RIO program: rimonabant in obesity) as well as a program in smoking cessation (STRATUS program). ***In 2005, registration dossiers were submitted in the United States and Europe. On February 17, 2006, an "approvable" letter for the weight management indication and a "non-approvable" letter for the smoking cessation indication were received from the FDA. Sanofi-aventis continues to work closely with the FDA on this matter.***

94. Filed together with Sanofi's Form 20-F were certifications from defendants Dehecq and Leroy in compliance with §§302 and 906 of the Sarbanes-Oxley Act of 2002. Included in the certifications were statements by Dehecq and Leroy asserting that they had reviewed Sanofi's Form

20-F and that the public “report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading.”

95. On April 28, 2006, Sanofi issued a press release announcing that rimonabant was recommended for approval in the European Union. The press release was also filed with the SEC as an exhibit to Sanofi’s Form 6-K on May 2, 2006, and stated in part:

Sanofi-aventis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending to grant marketing authorisation in the European Union for ACOMPLIA® (rimonabant 20mg) for the following indication: “As an adjunct to diet and exercise for the treatment of obese patients (BMI > 30kg/m²), or overweight patients (BMI > 27 kg/m²) with associated risk factors, such as type 2 diabetes or dyslipidemia (see section 5.1).” Section 5.1 of the Summary of Product Characteristics is the section of the labelling where detailed clinical study results supporting the indication are described. Importantly, statements in this section stipulate that half of the observed improvements in HbA1c, HDL cholesterol and triglycerides were beyond that expected from weight loss alone.

* * *

“ACOMPLIA® is an innovative, first-in-class treatment which will offer physicians a new approach to managing multiple cardiometabolic risk factors in patients with abdominal obesity who have other conditions such as type 2 diabetes, or unhealthy lipids.”

This press release served as a “booster shot” for the marketing of rimonabant as well as for Sanofi’s stock.

96. On May 5, 2006, defendants held a first quarter 2006 earnings conference call for analysts and investors during which defendants Spek and Leroy were present. During the conference call Spek and Leroy responded to questions from analysts regarding the launch date for rimonabant in the United States:

[PRUDENTIAL SECURITIES ANALYST] Thank you. A few questions. On Acomplia, are you guys still guiding for a second half [2006] launch in the U.S.?

[SPEK] Tim, thank you for your questions. *On Acomplia, I think we can say absolutely nothing else. We remain confident and prepared to launch Acomplia during the second half of 2005 – in 2006, excuse me. We remain in a permanent exchange with the FDA.*

In Europe, we are very actively now preparing for the first launches. If the usual delays are being respected, which are driven by the purely administrative recognition of the positive opinion which has been expressed on Acomplia, we are confident to launch in the first markets, then, in the period July/August. And those first markets, traditionally in Europe, are the United Kingdom and Germany.

* * *

[LEROY] In addition to that, because of this approval of Acomplia in Europe, we intend to launch, as again [Spek] mentioned, during the second part of the year in some European countries. And again, it is fair to say that we will put every mean [sic] which is necessary behind this product to make a success.

* * *

[MERRILL LYNCH ANALYST] Hi, good morning. Thanks for taking my questions. Firstly, on Acomplia, can you just confirm that you have had a meeting with the FDA post your approvable letter and that your second half launch guidance is based on the discussions you've had from that meeting?

Secondly, are you hiring additional reps in Europe for the Acomplia launch in the second half of the year?

* * *

[SPEK] On Acomplia, we don't intend to increase our rep sales force inside Europe consequent to the imminent launch, except perhaps small increases in smaller markets. But in the major markets we do this with our existing forces.

Then, on the ongoing conversations with the FDA, I cannot confirm to you that we had one meeting, as your question has been posed. I said earlier that we are in a permanent dialogue with the agency and I have nothing to add to this. *But as also previously stated, yes, we are still planning and we continue to plan for a launch also in the U.S. in the second half of 2006.*

97. Defendants' statements made between February 17, 2006 and May 5, 2006 were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of the RIO Studies, which showed a causal link between the use of rimonabant and depression. In fact, out of 1,253 psychiatric adverse events reported, which included various degrees of severity of depression, 1082 (88%) of them were suffered by patients in the rimonabant treatment group who did not have a baseline history of mood disorders;

(b) Prior to and during the Class Period, defendants were in possession of the efficacy and safety results of at least 12 rimonabant clinical studies, including the RIO Studies, which showed a causal link between rimonabant and suicidal ideation. In fact, the studies revealed 50 cases of suicidal ideation were associated with use of rimonabant, while only 14 were associated with placebo;

(c) During the RIO Studies, withdrawal rates for the RIO Studies ranged from 32% to 49% for the first year and 23% to 58% for the second year. Defendants failed to implement systematic follow-up procedures with patients who withdrew as a result of suffering an adverse psychiatric event, or with those patients that were excluded from the study by Sanofi because they went on a regimen of anti-depressants while a study was ongoing. As a result, defendants were unable to determine how long patients remained depressed and whether the severity of depression increased or decreased after withdrawal or exclusion from the study; and

(d) Immediately following February 17, 2006, defendants were in a continuous dialogue with the FDA regarding the undisclosed concerns about safety issues with rimonabant. During that period, the FDA regularly requested and defendants regularly submitted additional safety data concerning the association of rimonabant with adverse events, including, but not limited to, suicidality, seizures, depression, anxiety and insomnia, none of which was disclosed to investors.

98. As a result of defendants' false statements and omissions between February 17, 2006 and May 5, 2006, Sanofi's stock traded at artificially inflated levels. During the period, defendants' misleading statements and omissions of material information about rimonabant had a direct effect on Sanofi's stock price, which increased €2.00 per share.

False and Misleading Statements Made Between June 21, 2006 and November 9, 2006

99. On June 21, 2006, Sanofi issued a press release announcing that the Company received marketing approval for rimonabant in the European Union. In the press release, Sanofi discussed the benefits of rimonabant and the drug's safety and tolerability profile, stating:

First-in-class CB1 blocker approved for the treatment of obese patients, or overweight patients with associated risk factors, such as type 2 diabetes or dyslipidaemia

Sanofi-aventis announced today that the European Commission has granted marketing authorisation for ACOMPLIA® (rimonabant 20 mg/day) in all 25 European member states. ACOMPLIA®, discovered and developed by sanofi-aventis, is the first in a new class of drugs called CB1 blockers. ACOMPLIA® is indicated as an adjunct to diet and exercise for the treatment of obese patients (BMI \geq 30kg/m²), or overweight patients (BMI > 27kg/m²) with associated risk factors, such as type 2 diabetes or dyslipidaemia.

* * *

Safety and Tolerability

ACOMPLIA® 20mg has been evaluated for safety in over 6,300 patients. In placebo controlled studies the discontinuation rate due to adverse reactions was 15.7% for patients receiving ACOMPLIA®. The most common adverse events resulting in discontinuation were nausea, mood alteration with depressive disorders, anxiety and dizziness.

100. On August 2, 2006, defendants held a second quarter 2006 earnings conference call for analysts and investors during which defendants Spek and Leroy were present. During the conference call, Leroy and Spek responded to questions from analysts regarding the FDA's approval process regarding rimonabant:

[PRUDENTIAL SECURITIES ANALYST] And then on Acomplia, I'm hoping you can say whether you've submitted a response to the approvable letter with FDA, and should we expect an advisory committee on this drug before the end of the year?

[SPEK] First I start with the Acomplia question. We have no information at all on an advisory committee. My understanding is that an advisory committee always could appear but to date we have not the slightest indication that the FDA does so.

Now, the second part of your question, we don't understand the ongoing process with the FDA, in the way that the FDA has written us a letter and we write a letter in return and then the file is settled. ***It is a permanent dialogue between the agency and us, where we submit information. The FDA may ask additional questions on the basis of what has been submitted. And this is a process which is going on in a very intense and regular manner, but this is not a, let's say, one time event. We send data and then we get an answer.***

101. On October 18, 2006, Sanofi issued a press release discussing its objection to a German decision regarding public reimbursement for rimonabant. The press release was filed with the SEC as an exhibit to Sanofi's Form 6-K on October 19, 2006. The press release criticized the German authority's potential classification of rimonabant as a "lifestyle drug" and touted the benefits of rimonabant, stating:

The German Federal Joint Committee ("*Gemeinsamer Bundesausschuss*" – "*G-BA*") has announced today under its responsibility a recommendation to classify Acomplia under Section 34 of the Social Code Volume V ("*Sozialgesetzbuch Bd. V*" – "*SGB - V*"). Section 34 covers products viewed as lifestyle medications which are currently not reimbursed by the German statutory health insurance ("*Gesetzliche Krankenkasse*"). This decision is pending final ratification by the Ministry of Health within a period of two months. It becomes legally binding after publication in the Official Journal of the Government ("*Bundesanzeiger*").

Sanofi-aventis regards the proposed reimbursement classification of Acomplia as misplaced from a public health policy viewpoint and moreover as unlawful.

* * *

Sanofi-aventis firmly stands behind the important clinical benefits Acomplia offers to patients who are obese and overweight and suffer from other serious risk factors which can put them at risk of heart diseases and diabetes. Should the decision of the G-BA be approved, sanofi- aventis intends to challenge the reimbursement classification under Section 34 in court.

Sanofi-aventis is confident that the German Ministry of Health, in its review of the decision of the G-BA, will take all our scientific and medical arguments into due consideration. Pending the review of Ministry of Health and until publication of the final decision in the Bundesanzeiger, Acomplia will continue to be reimbursed in Germany according to the approved European Union label.

102. On October 27, 2006, Sanofi issued a press release announcing publication of the RIO-Diabetes Study in *The Lancet*. The press release was filed with the SEC as an exhibit to Sanofi's Form 6-K on October 31, 2006. The press release stated:

Sanofi-aventis announced today that the results of the RIO-Diabetes(1) trial were posted on *The Lancet* online edition (publication in the print edition is expected shortly). The one-year trial showed that rimonabant 20 mg once daily significantly improved several cardiometabolic risk factors.

* * *

The RIO-Diabetes study also assessed the safety and tolerability of rimonabant 20 mg once daily, 5 mg once daily and placebo, the results of which were consistent with the data from the entire RIO clinical trial programme which involved more than 6,600 patients. ***Side effects were mainly mild, transient, self-limiting and occurred early in the treatment period.*** The most frequent side effects included nausea (12.1% for rimonabant 20 mg once daily vs. 5.7% for placebo), dizziness (9.1% for rimonabant 20 mg once daily vs. 4.9% for placebo), diarrhoea (7.4% for rimonabant 20 mg once daily vs. 6.6% for placebo), vomiting (5.9% for rimonabant 20 mg once daily vs. 2.3% for placebo), self-reported hypoglycaemia (5.3% for rimonabant 20 mg once daily vs. 1.7% for placebo), fatigue (5.3% for rimonabant 20 mg once daily vs. 3.7% for placebo) and anxiety (5.0% for rimonabant 20 mg once daily vs. 2.6% for placebo).

103. During an October 31, 2006 conference call, defendant Spek responded to analysts' questions regarding rimonabant, stating:

[LEHMAN BROTHERS ANALYST] Okay. If I could ask a couple of questions please. Firstly, on your statement around the US Acomplia, could you just confirm that you[re] confident that you'll get a class one status for your review from the FDA, so we should therefore assume an action date at the very end of the year?

[SPEK] ***And last but not least, I have said that our people in Research and Regulatory have made their homework. Since we have had received the approvable letter on February 14, they have worked and they have submitted October 26 a complete response to this approvable letter.*** I really kindly ask you to understand that beyond this we will not speculate at all what the FDA now has to do or will do and within which timeline.

* * *

[HSBC ANALYST] Secondly, can I ask the Acomplia question again? I think the market is just trying to understand – everybody appreciates these negotiations are very difficult but obviously the market's just trying to understand, are we on a clock? Was additional data submitted? Was additional data not submitted?

* * *

[SPEK] Now on our country at large, I think you have used the word negotiation and I have to be clear that we are not in the process of negotiating this American authorities, the approval of the product.

[HSBC ANALYST] Yes.

[SPEK] That's not the way it work. We have received an approvable letter and usually, and also in this case, an approvable letter contains questions. We have answered to those questions *and as the approvable letter did not ask for new additional clinical trials, consequently it is easier for me to say that we have not submitted new data in this respect.*

I may refer perhaps to, an erroneous report on the potential usage of European safety data, which has been issued a couple of weeks ago by Bloomberg. You may have seen that we have made a [inaudible] to this because if this was evidence, it was flawed.

So, to sum it up. We have made our homework. We have answered the questions. We have submitted this and all speculations from there on is useless and we will not do so.

104. On the same day as the October 31, 2006 conference call, Sanofi issued a press release announcing the Company's earning for the first three quarters of 2006. The press release was filed with the SEC as an exhibit to Sanofi's Form 6-K on the same day. The press release discussed the success of the European launch of rimonabant and announced the submission of the Company's October 26, 2006 response to the FDA February 17, 2006 approvable letter. The press release stated:

Regarding the ongoing review of rimonabant® in the United States, the company has submitted on October 26, 2006 the complete response to the approvable letter received from the FDA on February 17, 2006.

105. In reaction to defendants' October 31, 2006 announcement, Sanofi's stock price decreased approximately 3.0%, to close at €66.60 at the end of the trading day on heavy volume (15.4 million shares).

106. On November 9, 2006, defendant Cluzel and Sanofi representative Pierre Chancel participated in a conference call hosted by Credit-Suisse. During the conference call, defendants presented slides detailing the market for rimonabant, which pitched the drug's efficacy and safety profile. During that presentation, defendant Cluzel made the following statements about the RIO Studies:

- *No increased adverse event reporting or discontinuation rate during second year of treatment.*
- *Adverse events usually occurred during first months and were generally of mild to moderate intensity.*
- *Safety profile in year two was generally not different from that of placebo or year one.*
- *Long term exposure did not identify new or increased risks.*

107. Defendants' statements made between June 21, 2006 and November 9, 2006 were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of the RIO Studies, which showed a causal link between the use of rimonabant and depression. In fact, out of 1,253 psychiatric adverse events reported, which included various degrees of severity of depression, 1082 (88%) of them were suffered by patients in the rimonabant treatment group who did not have a baseline history of mood disorders;

(b) Prior to and during the Class Period, defendants were in possession of the efficacy and safety results of at least 12 rimonabant clinical studies, including the RIO Studies,

which showed a causal link between rimonabant and suicidal ideation. In fact, the studies revealed 50 cases of suicidal ideation were associated with use of rimonabant, while only 14 were associated with placebo;

(c) During the RIO Studies, withdrawal rates for the RIO Studies ranged from 32% to 49% for the first year and 23% to 58% for the second year. Defendants failed to implement systematic follow-up procedures with patients who withdrew as a result of suffering an adverse psychiatric event, or with those patients that were excluded from the study by Sanofi because they went on a regimen of anti-depressants while a study was ongoing. As a result, defendants were unable to determine how long patients remained depressed and whether the severity of depression increased or decreased after withdrawal or exclusion from the study; and

(d) Immediately following February 16, 2006, defendants were in a continuous dialogue with the FDA regarding undisclosed concerns about safety issues with rimonabant. During that period, the FDA regularly requested and defendants regularly submitted additional safety data concerning the association of rimonabant with adverse events, including, but not limited to, suicidality, seizures, depression, anxiety and insomnia, none of which was disclosed to investors.

108. As a result of defendants' false statements and omissions between June 21, 2006 and November 9, 2006, Sanofi's stock continued to trade at artificially inflated levels.

False and Misleading Statements Made Between December 5, 2006 and February 13, 2007

109. On December 5, 2006, defendants held a conference call for analysts and investors during which the results of another rimonabant trial, known as SERENADE, was presented by defendant Greene. During the conference call, Greene continued to tout purportedly positive study results for rimonabant:

By way of background, if we go to the next slide, we previously studied the effect of rimonabant in type 2 diabetes in a study called RIO-Diabetes which has been recently published. And this demonstrated, that in patients with more advanced

Diabetes, that is patients who were already on treatment with an oral anti-diabetic but were, nevertheless, poorly controlled, that the addition of rimonabant, compared to placebo, **resulted in a consistent and persistent improvement in hemoglobin A1c of about 0.7% compared to placebo, which is in the range of most oral anti-diabetic treatments.** But, again, these were patients who were already on background therapy with either Metformin or sulphonylurea.

* * *

The next slide takes us into the consideration of the safety profile that we saw in this study. **Overall, the safety profile was consistent with what we've seen in the past, which we found reassuring.** This slide demonstrates the number of patients who had any adverse event, patients with serious adverse events and patients who discontinued due to adverse events; the last column. And I would call your attention to that. We've, again, seen, always seen, a slight increase in the percentage of patients who discontinue due to adverse events with rimonabant.

The next slide demonstrates the types of adverse events that we've seen. These are greater than 5% in any group. **And, again, consistent with the previously demonstrated safety profile, some increase in dizziness, nausea, which is usually mild, self-limited, normally one episode of slight nausea for example.** There is an imbalance as well, in this case in upper respiratory tract infections. We've not seen that previously. It may just be a play of chance. There is a slight increase in anxiety, a slight increase in depressed mood. And these are, again, consistent with the safety profile that we have previously reported.

If we focus down into the psychiatric disorder we see, again, a similar numerical imbalance that we've reported previously with one, I think, important and somewhat reassuring component here. **Although there was an increase in the frequency of depressed mood, 5.8% versus 0.7%, in this study we had emphasized the need to evaluate depressed mood and depression in a consistent and rigorous way. And what we actually see, although, there is an increase in the frequency of depressed mood, there is no increase in cases of depression. And, in fact, there is a numerically smaller number of cases of depression in rimonabant 20mg, indicating that whatever we're seeing in this general area, seems to be mild and, perhaps, more of a tolerability issue than a safety issue.**

110. During the December 5, 2006 conference call, defendants Cluzel and Greene answered analysts' questions regarding rimonabant, including questions about the results of the SERENADE study with regard to depressed mood and depression, stating:

[REDBURN ANALYST] So in terms of the depression, we should be looking at the lower set of figures for Acomplia in terms of comparing to the European label, and looking at the more serious, rather just dysthymic side effects that the medical – the psychiatric disorder?

* * *

[REDBURN ANALYST] Sorry. I mean the European label, for example, lists the incidents of depression as 3.2% with Acomplia versus 1.6 I think it was with placebo.

[GREENE] Yes.

[REDBURN ANALYST] We – the comparable figure from this trial should be – shouldn't be the 5.8. It should be the, I can't remember, 2.4. Or is it slightly different then because you've mentioned definition?

[GREENE] I think we've refined the way that we've asked investigators and instructed investigators to report this. So I think you have to take each trial on its own merits, and that's why we have a placebo group. *And so what I think this demonstrates, at least in my way of thinking, is that whatever we're seeing in this realm is relatively mild. We'd said it before that we thought it was mild and self-limiting. The fact that we see the imbalance in depressed mood and we don't see it in depression just – it's reassuring.*

* * *

[LEHMAN BROTHER ANALYST] Can I just also ask, with the six month study, is there any suggestion that the problem occurs early on, people then are happier, therefore, this was skewed? Or are you giving me the usage at that end point? So, presumably one would assume that it has built up this level by six months.

[GREENE] . . . I think the best place to look at that is in what we've published with the two year studies. And in those two year studies, *when you look at the question of depression and depressed mood, in the second year there is no difference from placebo*. So I think, again, you are right in saying this is a short study, and probably not the best place to look at that question. But I think the longer studies are – speak for themselves.

[CLUZEL] Yes, still also Jo [Lehman Brother Analyst], you have to remember that it was a simulated question specifically about depressed mood. So, from where you know that when you are asking if you have something you always increase the number of reporting. So, I don't think that the study is down-sizing the event.

111. On December 5, 2006, Sanofi also issued a press release concerning the results of the SERENADE trial. The press release was filed with the SEC as an exhibit to Sanofi's Form 6-K on December 8, 2006. The press release was entitled "New Data Shows Acomplia (Rimonabant) Benefited Patients with Type 2 Diabetes by Improving Blood Sugar Control, Reducing Weight and Acting on Other Cardiometabolic Risk Factors," and stated:

Sanofi-aventis announced today that new data on rimonabant, its first-in-class cannabinoid type 1 (CB1) receptor blocker, showed that patients with type 2 diabetes not currently treated with anti-diabetic medications experienced significant improvements in blood sugar control and weight as well as other risk factors such as HDL-cholesterol (good cholesterol) and triglycerides when compared to placebo. The study, called SERENADE, was presented today at the International Diabetes Federation (IDF) World Diabetes Congress in Cape Town, South Africa. SERENADE is the second study demonstrating that rimonabant significantly improved blood sugar levels in people with type 2 diabetes.

In the SERENADE study, treatment-naïve type 2 diabetes patients receiving rimonabant 20mg per day for a duration of six months significantly lowered their HbA1c levels by 0.8% from a baseline value of 7.9 as compared to a reduction of 0.3% in the placebo group ($p=0.002$). In addition, patients with an HbA1c level greater than or equal to 8.5% at baseline, significantly reduced their HbA1c by 1.9% with rimonabant as compared to 0.7% with placebo ($p<0.0009$). Over 50% of patients in the rimonabant arm of the trial achieved HbA1c levels below 7%, the target for good glucose control as recommended by the American Diabetes Association (ADA)(1). Importantly, these improvements in blood glucose control were accompanied by significant and clinically meaningful reductions in body weight of 6.7 kg (14.8 lbs) in patients treated with rimonabant 20 mg, while those patients on placebo lost only 2.7 kg (5.95 lbs) ($p<0.0001$).

* * *

The most common side effects with placebo and rimonabant 20 mg reported in the SERENADE trial were dizziness (2.1% vs. 10.9%), nausea (3.6% vs. 8.7%), nasopharyngitis (7.9% vs. 7.2%), upper respiratory tract infection (2.7 % vs. 7.2%), anxiety (3.6% vs. 5.8%), depressed mood (0.7% vs. 5.8%), and headache (6.4% vs. 3.6%). The rate of serious adverse events was 3.6% for patients in the placebo arm versus 6.5% for patients in the rimonabant 20 mg.

112. On December 8, 2006, Sanofi issued a press release entitled “Rimonabant Update in the United States.” The press release was filed with the SEC as an exhibit to Sanofi’s Form 6-K on the same day. In the press release, Sanofi announced that its October 26, 2006 submission to the FDA was considered by the FDA to be a “complete, class 2 response to the FDA February 17, 2006 action letter,” and that the FDA was expected to take action on the rimonabant NDA by April 26, 2007.

113. On February 12, 2007, Sanofi issued a press release, entitled “Rimonabant USA: Update.” The press release was filed with the SEC as an exhibit to Sanofi’s Form 6-K on February 13, 2007. The press release stated:

Sanofi-aventis announced today that the review period of rimonabant in the United State has been extended by three months, until July 27, 2007.

The Group also announced the submission of the SERENADE clinical study report today in the rimonabant NDA submitted to the FDA.

Rimonabant is a first-in-class cannabinoid type 1 receptor discovered and developed by sanofi-aventis.

114. On February 13, 2007, defendants held a 2006 earnings conference call for analysts and investors. Defendants Dehecq, Le Fur, Spek and Leroy attended the conference and presented a slide show which included details about rimonabant studies conducted in Japan. Defendants’ presentation emphasized rimonabant’s consistent efficacy across studies and populations and that the Japan studies confirmed a good safety profile. During the February 13, 2007 conference call, defendants discussed rimonabant and the results from the Japan studies:

[SPEK] Now on Acomplia some words. You see that we have launched Acomplia during the second half, mainly during in the fourth quarter, now in 12 countries. And you have read during the last weeks that the launch in France is imminent. And we prepare for this launch at the beginning of March.

* * *

[CLUZEL] ***In terms of safety, well, of course, we should have started this development in Japan. Great safety profile you can see here. There are fewer patients that exit the study with adverse effects in the 20mg group than in the placebo group.***

What’s also interesting, difficult to know whether it’s specific to the Japanese population, the absence of nausea in the list of adverse events for depression. This may be a cultural factor in so far as depression is not widely reported in Japan. But for nausea we need to continue development. We currently have studies underway in phase III in Japan. It’d be interesting to see if there really is a different nausea. So that was Acomplia.

* * *

[EXANE BNP PARIBAS ANALYST] First of all about Acomplia. Could you tell me what the main reason is for the supplementary review issued by the FDA.

* * *

[CLUZEL] Well, when it comes to Acomplia, we decided long since not to make any comments on FDA decisions, but there are two points. A, there will be a three-month extension of the date. And then secondly we always have a permanent rolling-up date. Well, in Europe it's not permanent, either every four months or every six month. But [inaudible] have permanent updates on the safety of the product. In this case, it's the efficacy, which is what we're looking at.

Well, turning to Acomplia results, I think no one has any doubts as to its efficacy. When it comes to tolerance to this drug, in Europe we have seen no particular tolerance signals aside from the elements which were in the initial file. I think that's important to underline. So for the time being, we're simply waiting for registration in the United States. And this will come about sooner or later, hopefully in the course of this year.

* * *

[CLUZEL] Just a brief additional point regarding Acomplia. Of course we do not comment, nor will we ever comment [on] FDA decisions. We would, however, like to point out that in recent times there have been several instances where new application – authorization demands have been extended by three-month periods. *Needless to say, we are extremely optimistic as to obtaining an NDA for Rimonabant.*

115. On February 13, 2007, Sanofi issued an earnings press release which discussed rimonabant, including the results of the SERENADE trials, and reiterated the FDA's acceptance of the Company's October 26, 2006 response to the FDA's February 17, 2006 letter. The press release was filed on the same day with the SEC as an exhibit to Sanofi's Form 6-K. The press release stated in part:

Acomplia® (rimonabant): Results of a 526-patient phase IIb study conducted in Japan provided the first data in an Asian patient population. *The study demonstrated an impressive consistency in terms of benefits on cardiometabolic risk factors with results of previous studies.* In addition, a reduction in visceral fat was observed in patients who underwent a CT-scan. *Rimonabant demonstrated a good safety profile.* Phase III trials are currently in progress for two indications: diabetes and weight management. The company intends to submit the registration file in 2009 in Japan.

116. Defendants' statements made between December 5, 2006 and February 13, 2007 were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of the RIO Studies, which showed a causal link between the use of rimonabant and depression. In fact, out of 1,253 psychiatric adverse events reported, which included various degrees of severity of depression, 1082 (88%) of them were suffered by patients in the rimonabant treatment group who did not have a baseline history of mood disorders;

(b) Prior to and during the Class Period, defendants were in possession of the efficacy and safety results of at least 12 rimonabant clinical studies, including the RIO Studies, which showed a causal link between rimonabant and suicidal ideation. In fact, the studies revealed 50 cases of suicidal ideation were associated with use of rimonabant, while only 14 were associated with placebo;

(c) During the RIO Studies, withdrawal rates for the RIO Studies ranged from 32% to 49% for the first year and 23% to 58% for the second year. Defendants failed to implement systematic follow-up procedures with patients who withdrew as a result of suffering an adverse psychiatric event, or with those patients that were excluded from the study by Sanofi because they went on a regimen of anti-depressants while a study was ongoing. As a result, defendants were unable to determine how long patients remained depressed and whether the severity of depression increased or decreased after withdrawal or exclusion from the study; and

(d) Immediately following February 17, 2006, defendants were in a continuous dialogue with the FDA regarding the undisclosed concerns about safety issues with rimonabant. During that period, the FDA regularly requested and defendants regularly submitted additional safety

data concerning the association of rimonabant with adverse events, including, but not limited to, suicidality, seizures, depression, anxiety and insomnia, none of which was disclosed to investors.

117. As a result of defendants' false statements and omissions between December 5, 2006 and February 13, 2007, Sanofi's stock continued to trade at artificially inflated levels.

False and Misleading Statements Made Between March 26, 2007 and May 3, 2007

118. On March 26, 2007, Sanofi issued a press release entitled "Rimonabant USA: Update – Sanofi-aventis acknowledges FDA announcement of an Advisory Committee Meeting for rimonabant." The press release was filed with the SEC as an exhibit to Sanofi's Form 6-K on March 26, 2007. The press release stated:

Sanofi-aventis announced today the FDA notice for its first in class CB1 receptor antagonist rimonabant, now scheduled for an Endocrinologic and Metabolic Drugs Advisory Committee Meeting to be held on June 13, 2007.

The Committee will discuss the efficacy and safety of rimonabant in obesity.

Sanofi-aventis is pleased to have the opportunity to present its data on rimonabant and to exchange with experts.

119. On April 4, 2007, Sanofi filed with the SEC its Form 20-F for the fiscal year ended December 31, 2006. Sanofi's Form 20-F, signed by defendant Le Fur, contained the following statements about rimonabant:

Throughout an extensive Phase III clinical trial (RIO program) it has been shown that treatment with [rimonabant] results in reduction in weight and waist circumference (a key marker of abdominal obesity), together with improvements on HDL-C, TG and glycemic control in a broad range of patients with multiple cardio-metabolic risk factors. Approximately half of the improvements seen with [rimonabant] on HDL-C, TG and HbA1C (a marker of glycemic control) is believed to arise directly from blockade of peripheral CB-1 receptors in metabolically active tissues such as the liver, adipose tissues and skeletal muscles.

* * *

In Japan, results of a 526-patient Phase IIb study demonstrated an impressive consistency in terms of benefits on weight and cardio-metabolic risk factor reduction

as compared to the results of previous European and U.S. studies. ***Rimonabant demonstrated a good safety profile in this population.***

120. Filed together with Sanofi's Form 20-F were certifications from defendants Le Fur and Leroy in compliance with §§302 and 906 of the Sarbanes-Oxley Act of 2002. Included in the certifications were statements by Le Fur and Leroy asserting that they had reviewed Sanofi's Form 20-F and that the public "report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading."

121. On May 2, 2007, defendants held a first quarter 2007 conference call for analysts and investors. Defendants Spek and Leroy attended the conference call and made a presentation emphasizing the strong market for rimonabant in Europe and the large population of potential patients that would benefit from taking the drug. During the conference call, defendants also reported on the upcoming FDA Advisory Committee meeting planned for June 13, 2006. As noted by defendant Spek:

Of course, the big event in context with Acomplia for the second, the ongoing quarter will be the FDA advisory committee planned for June 13. We are, of course, actively preparing for this meeting. ***We welcome the opportunity to show all our data and to discuss it in public.*** We believe that this, in fact, is the best way to find the right decision for this very important product.

122. On May 3, 2007, Sanofi issued a press release announcing its first quarter 2007 results. The press release was filed with the SEC as an exhibit to Sanofi's Form 6-K on May 3, 2007. The press release stated in part:

Acomplia® is now available in over 10 European countries. It has been available in France since March 2007, and is reimbursable for obese patients with type 2 diabetes uncontrolled by metformin or sulphonylurea. In early April, the product was granted marketing approval in Switzerland and is reimbursed for the treatment of type 2 diabetics overweight patients and for the treatment of patients with obesity. At the end of April, Acomplia has been approved in Brazil for the treatment of obese patients, or overweight patients with associated risk factors, such

as type 2 diabetes or dyslipidemia. Acomplia® is also available in Argentina, Mexico and Chile. First-quarter net sales totaled €15 million.

* * *

In the United States, rimonabant is on the agenda for the Endocrinologic and Metabolic Drugs Advisory Committee Meeting to be held on June 13, 2007. The FDA action letter is due on July 26, 2007.

123. Defendants' statements made between March 26, 2007 and May 3, 2007 were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of the RIO Studies, which showed a causal link between the use of rimonabant and depression. In fact, out of 1,253 psychiatric adverse events reported, which included various degrees of severity of depression, 1082 (88%) of them were suffered by patients in the rimonabant treatment group who did not have a baseline history of mood disorders;

(b) Prior to and during the Class Period, defendants were in possession of the efficacy and safety results of at least 12 rimonabant clinical studies, including the RIO Studies, which showed a causal link between rimonabant and suicidal ideation. In fact, the studies revealed 50 cases of suicidal ideation were associated with use of rimonabant, while only 14 were associated with placebo;

(c) During the RIO Studies, withdrawal rates for the RIO Studies ranged from 32% to 49% for the first year and 23% to 58% for the second year. Defendants failed to implement systematic follow-up procedures with patients who withdrew as a result of suffering an adverse psychiatric event, or with those patients that were excluded from the study by Sanofi because they went on a regimen of anti-depressants while a study was ongoing. As a result, defendants were

unable to determine how long patients remained depressed and whether the severity of depression increased or decreased after withdrawal or exclusion from the study; and

(d) Immediately following February 17, 2006, defendants were in a continuous dialogue with the FDA regarding the undisclosed concerns about safety issues with rimonabant. During that period, the FDA regularly requested and defendants regularly submitted additional safety data concerning the association of rimonabant with adverse events, including, but not limited to, suicidality, seizures, depression, anxiety and insomnia, none of which was disclosed to investors.

124. As a result of defendants' false statements and omissions between March 26, 2007 and May 3, 2007, Sanofi's stock traded at artificially inflated levels. During the period, defendants' misleading statements and omissions of material information about rimonabant had a direct effect on Sanofi's stock price, which increased €3.23 per share.

DISCLOSURE OF THE FRAUD

125. On June 13, 2007, defendants issued a press release stating that the FDA's Endocrinologic and Metabolic Advisory Committee did not recommend approval for rimonabant as a treatment for obesity in the United States. On that day, the 14-member Advisory Committee conducted a public hearing during which various healthcare professionals, including Sanofi employees, FDA officials and representatives of public interest groups provided testimony. After deliberating on the day's testimony and presentations, the Advisory Committee was asked to vote on the following question:

[B]ased on the current data . . . do you believe rimonabant has a favorable risk/benefit profile and should be approved for the indication of weight management in individuals?

126. According to the transcript of the June 13, 2007, the results of the vote were both unanimous and unequivocal:

DR. WOOLF: No.

DR. GILMAN: No.

DR. ROSEN: Dr. Rosen says no.

DR. KREISBERG: No.

DR. CIRAULO: No.

MS. COFFIN: No.

DR. WANG: No.

DR. GOODMAN: No.

DR. PROSCHAN: No.

DR. FLEGLER: No.

DR. HENDERSON: No.

DR. CARPENTER: No.

DR. BURMAN: No.

Dr. Rosen, the chair of the Advisory Committee, then entered Dr. Kirsch's "no" vote on the record.

127. As a result of the disclosures during the FDA Advisory Committee's public hearing on June 13, 2007, Sanofi's stock price, as traded on the Euronext in Paris, dropped from a June 13, 2007 close of €67.26 per share, to a close of €63.00 per share on June 14, 2007. Beginning on June 13, 2007, Sanofi's ADSs dropped from a June 12, 2007 close of \$44.38 per share to a June 14, 2007 close of \$41.33 per share. The decreases were mirrored by the Company's depository receipts and depository shares trading around the globe.

128. The decrease in Sanofi's securities beginning on June 13, 2007 was a direct result of the artificial inflation caused by defendants' false and misleading Class Period statements and omissions coming out of the Company's stock price. Indeed, the FDA Advisory Committee declined to recommend rimonabant for approval as an obesity treatment because of the previously undisclosed clinical safety data offered to the FDA revealed a causal connection between the drug's

use and depression and suicidal ideation and that the Company's clinical trials suffered from significant procedural flaws.

129. The June 13, 2007 Advisory Committee vote, for all intents and purposes, was a rejection of Sanofi's NDA for rimonabant as treatment of obesity in the United States and raised serious questions about the Company's ability to deliver revenue and profit growth in the future. On June 14, 2007, Max Herrmann of ING Wholesale Banking reported:

Acomplia: sales forecasts cut dramatically. We have reduced our risk-adjusted sales forecasts for [rimonabant] to €1.2bn in 2012F (previously €2.7bn) following an FDA advisory committee's unanimous vote not to recommend approval of the drug.

* * *

Since the advisory committee's recommendations are usually followed, the decision leaves almost no chance that [rimonabant] will be approved in the US in the near term.

130. On June 14, 2007, Eric Le Berrigaud of Raymond James Euro Equities commented on the FDA Advisory Committee's vote and threat to Sanofi's drug pipeline:

The answer was a resounding "no", as the experts voted 14-0 against.

* * *

[T]he vote is likely to make a lot of noise in the press, both general and specialist.

* * *

We have decided to remove all sales contributions from rimonabant in the US (versus USD2.8bn in 2015 until now) and are reducing our estimates for Europe and elsewhere significantly. ***In all, we are cutting our peak sales estimate from EUR4.1bn to EUR800m in 2016.***

* * *

Sanofi-Aventis is now in a sticky situation. Although it is important to secure mature products such as Lovenox and Plavix, ***the main question is whether the R&D pipeline will be able to deliver.***

131. On June 14, 2007, Peter Düllmann of Sal. Oppenheim concluded that a marked downturn in Sanofi's stock price was to be expected as a result of the FDA Advisory Committee's decision, adding: ***"Given the already difficult situation surrounding Plavix (generic challenge) this is particularly negative news for Sanofi. . . . Taking out Zimulti US-sales would erase about €4 per share in FV."***

132. On June 14, 2007, M2 Presswire reported:

U.S.-listed shares of French drugmaker Sanofi-Aventis dropped for the second straight day on Thursday June 14, 2007 after an advisory panel to the Food and Drug Administration unanimously recommended against approval of weigh-loss drug Acomplia

* * *

Sanofi . . . said it would work "closely" with the FDA to address the committee's recommendations, though most outside observers find that the chances for the drug to win approval are virtually zero.

Goldman Sachs analysts had estimated 2 billion euros (\$2.7 billion) of global sales of the drug in 2011 – or about half of the [Company's] sales growth from 2006 to 2011.

133. On June 29, 2007, Sanofi completely withdrew its NDA for rimonabant, which means that the FDA will not meet to further consider approval of the drug. In essence, the Company's decision is a death-blow to rimonabant in the United States in the near term.

134. On July 2, 2007, Natixis Securities reported that the Company's "withdrawal of the rimonabant file in the USA should not come as a surprise following its unanimous rejection. . . . We do not think the group will be able to resubmit the file until 2010 at best."

135. In November 2007, *The Lancet* published the results of its analysis of the data contained in the RIO Studies. The article stated in part:

Our findings suggest that 20 mg per day rimonabant increases the risk of psychiatric adverse events – [i.e.,] depressed mood disorders and anxiety – despite depressed mood being an exclusion criterion in these trials. Taken together with the recent [FDA] finding of increased risk of suicide during treatment with

rimonabant, we recommend increased alertness by physicians to these potentially severe psychiatric adverse reactions.

136. Also in November 2007, the *British Medical Journal* posted the results of a meta analysis of compounds for the treatment of obesity and offered the following conclusions regarding rimonabant:

Adverse effects – The most worrying adverse effect was an increased incidence of psychiatric disorders (depression, anxiety, irritability, aggression).

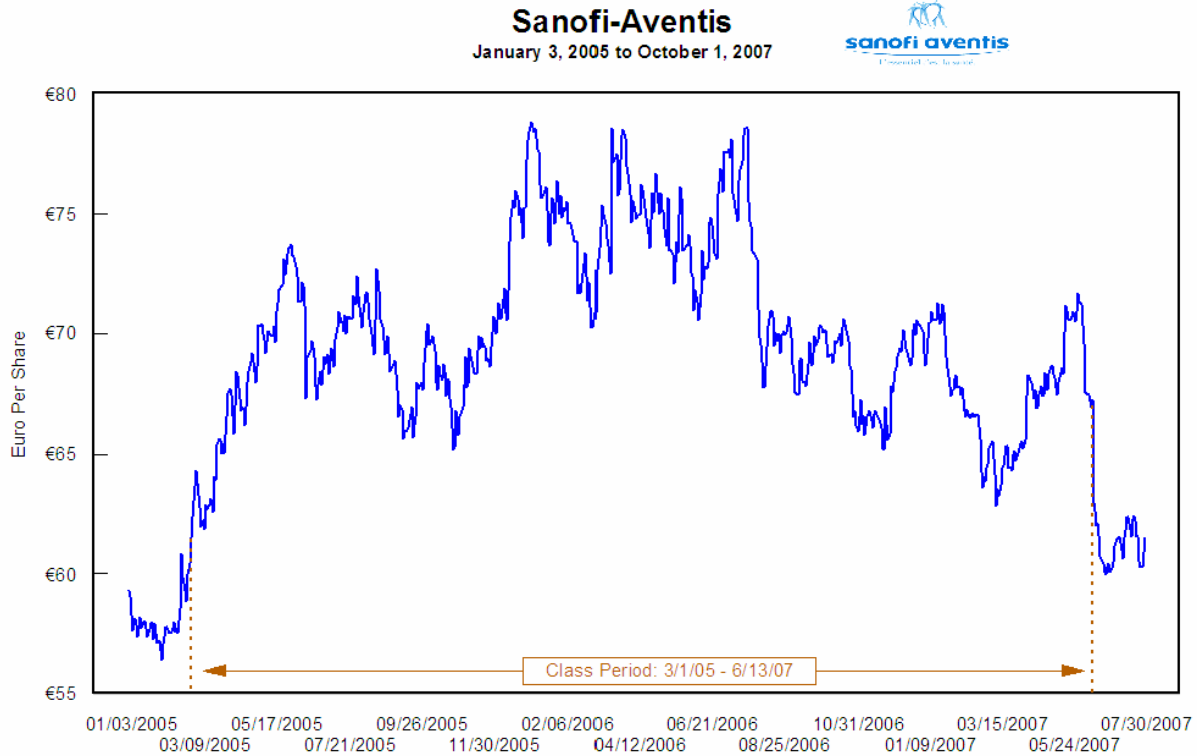
* * *

As the patients enrolled in the rimonabant trials were carefully screened to exclude those with major psychiatric disease, the risk of mood disorders with rimonabant might be underestimated.

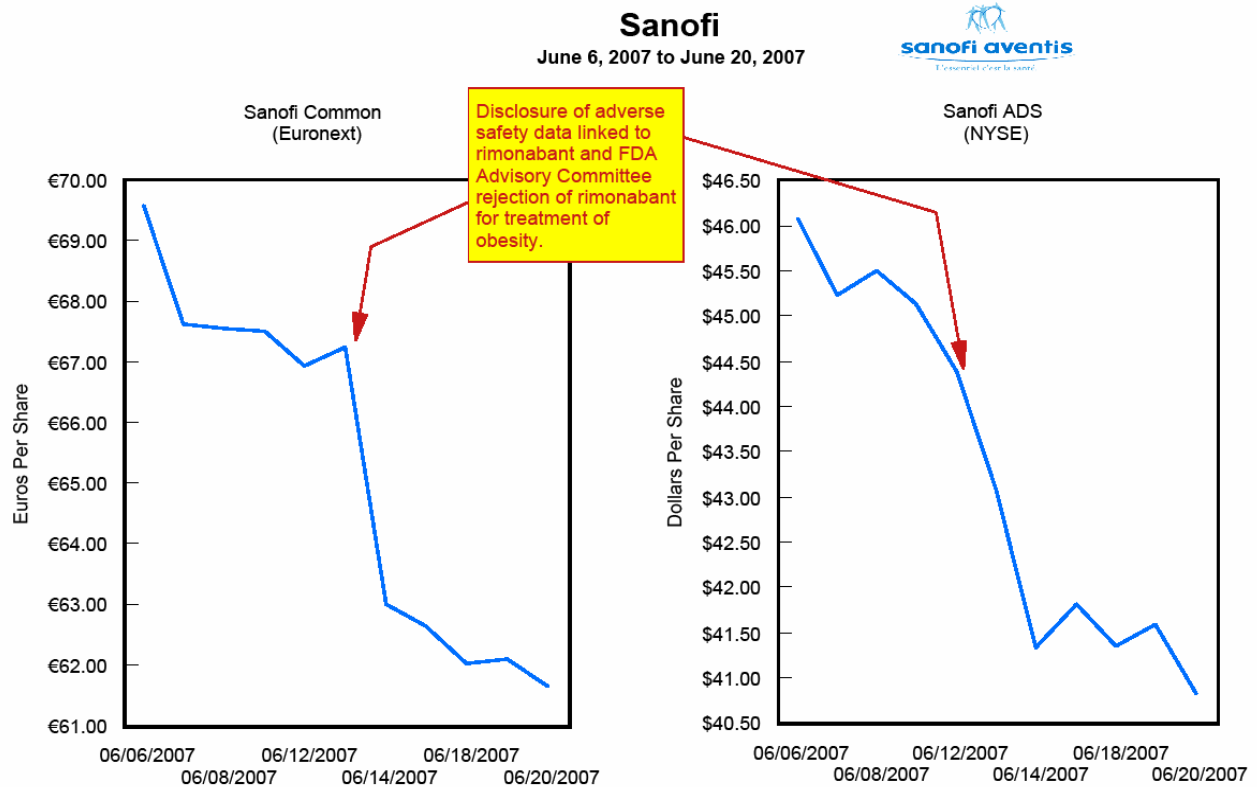
PROXIMATE LOSS CAUSATION/ECONOMIC LOSS

137. During the Class Period, as detailed herein, defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially inflated and maintained Sanofi's stock price and operated as a fraud or deceit on Class Period purchasers of Sanofi's publicly traded securities by misrepresenting and omitting material information about suicidality and serious adverse side effects associated with rimonabant. When defendants' prior misrepresentations and omissions were disclosed and it became apparent to the market that rimonabant suffered from serious side effects and Sanofi was unlikely to be able to market the drug in the United States, Sanofi's stock price fell precipitously as the prior artificial inflation came out of the price. As a result of their purchases of Sanofi stock during the Class Period, plaintiffs and other members of the Class, as defined in ¶147, suffered economic loss, *i.e.*, damages, under the federal securities laws.

138. Defendants' false statements and omissions, identified herein at ¶¶66-124, had the intended effect and caused Sanofi stock to trade at artificially inflated levels during the Class Period, as reflected in the following chart:



139. As a direct result of the June 13, 2007 disclosures about serious adverse side effects associated with rimonabant, and the FDA Advisory Committee's unanimous vote to deny approval for rimonabant as a treatment for obesity, Sanofi's stock price dropped immediately. Sanofi's ADSs traded on the NYSE began to drop on June 13, falling from a June 12 close of \$44.38 per share to a June 14 close of \$41.33. Trading volume increased from 2.67 million shares traded on June 12, to 8.88 million traded on June 13 and 12.19 million shares traded on June 14 as the market reacted to the news about rimonabant. On the Euronext, Sanofi's share dropped from €67.26 to €63.00 on June 14, 2007 as trading volume increased more than 700%. Sanofi's stock price continued to lose value as the impact of the negative information was digested by the market. By June 25, 2007, Sanofi shares were trading below €60.00 per share. As identified in the charts below, these drops removed the inflation from Sanofi's stock price, causing real economic loss to investors who had purchased the stock during the Class Period.



140. The decline in Sanofi's stock price at the end of the Class Period was a direct result of the nature and extent of defendants' prior false statements and omissions being revealed to investors and the market. The timing and magnitude of Sanofi's stock price declines negate any inference that the loss suffered by plaintiffs and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the defendants' fraudulent conduct. Indeed, on June 14, 2007, the same day Sanofi's stock price fell more than €4.26 per share a result of defendants' fraud being revealed, the Euronext 100 index moved slightly up on average volume. The economic loss, *i.e.*, damages, suffered by plaintiffs and other members of the Class, was a direct result of defendants' fraudulent scheme to artificially inflate Sanofi's stock price and maintain the price at artificially inflated levels and the subsequent significant decline in the value of Sanofi's stock when defendants' prior misrepresentations and omissions were revealed.

NO SAFE HARBOR

141. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as “forward-looking statements” when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Sanofi who knew that those statements were false when made.

FRAUD-ON-THE-MARKET PRESUMPTION

142. Plaintiffs will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) The omissions and misrepresentations were material;
- (c) The Company’s securities traded in efficient markets;
- (d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company’s securities; and
- (e) Plaintiffs and other members of the Class purchased Sanofi securities between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

143. At all relevant times, the markets for Sanofi securities were efficient for the following reasons, among others:

(a) Sanofi common stock met the requirements for listing, and was listed and actively traded, on the NYSE and Euronext in Paris;

(b) Sanofi depository shares and depository receipts met the requirements for listing, and were listed and actively traded on foreign exchanges around the globe; and

(c) Sanofi common stock, depository shares and depository receipts were regularly followed by securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and customers of their respective brokerage firms;

(d) Sanofi regularly communicated with the public and investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

144. As a result, the markets for Sanofi securities digested current information with respect to Sanofi from publicly available sources and reflected such information in Sanofi's securities prices. Under these circumstances, all purchasers of Sanofi securities during the Class Period suffered similar injury through their purchase of securities at artificially inflated prices and a presumption of reliance applies.

CLASS ALLEGATIONS

145. Sanofi regularly communicated with the public and investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

146. As a result, the market for Sanofi securities digested current information with respect to Sanofi from publicly available sources and reflected such information in Sanofi's securities prices. Under these circumstances, all purchasers of Sanofi securities during the Class Period suffered similar injury through their purchase of securities at artificially inflated prices and a presumption of reliance applies.

147. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of; (a) all United States-based purchasers and/or acquirers of Sanofi securities on the NYSE; (b) all United States-based purchasers and/or acquirers of Sanofi securities on any foreign exchange; and (c) all foreign purchasers and/or acquirers of Sanofi securities on the NYSE, during the Class Period who were damaged thereby (the "Class"). Excluded from the Class are defendants, the officers and directors of the Company, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

148. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Sanofi's ADSs were actively traded on the NYSE and the Company's common stock and depository shares and receipts were exchanged around the globe. While the exact number of Class members is unknown to plaintiffs at this time and can only be ascertained through appropriate discovery, plaintiffs believe that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Sanofi or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

149. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class were similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

150. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

151. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) Whether the federal securities laws were violated by defendants' acts and omissions as alleged herein;

(b) Whether statements made by defendants to the investing public during the Class Period misrepresented and omitted material facts about the business and operations of Sanofi; and

(c) To what extent the members of the Class have sustained damages and the proper measure of damages.

152. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

**Violation of Section 10(b) of the Exchange Act and Rule 10b-5
Promulgated Thereunder Against All Defendants**

153. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

154. During the Class Period, Sanofi and the individual defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (a) deceive the investing public, including plaintiffs and other members of the Class, regarding rimonabant and Sanofi's business, operations, financial prospects and the intrinsic value of Sanofi's publicly traded securities; (b) artificially inflate and maintain the market price of Sanofi's securities; and (c) cause plaintiffs and other members of the Class to purchase Sanofi's securities at artificially inflated prices and, as a result, suffer economic losses when the truth and impact about defendants' fraud was revealed. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

155. Defendants: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (c) engaged in acts, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's publicly traded securities in an effort to maintain artificially high market prices for Sanofi's publicly traded securities in violation of §10(b) of the Exchange Act and Rule 10b-5. All defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

156. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a

continuous course of conduct to conceal adverse material information about rimonabant as specified herein.

157. These defendants employed devices, schemes and artifices to defraud, while in possession of material, adverse, non-public information and engaged in acts, practices and a course of conduct as alleged herein in an effort to assure investors of Sanofi's value and performance and continued growth, which included the making of, or the participation in the making of, untrue statements of material fact and omitting to state material facts necessary in order to make the statements made about Sanofi and rimonabant, in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Sanofi's publicly traded securities during the Class Period.

158. Each of the individual defendants' primary liability, and controlling person liability, arises from the following facts: (a) the individual defendants were high-level executives and, in certain circumstances, directors at the Company during the Class Period and members of the Company's senior management team; (b) each of these defendants, by virtue of his or her responsibilities and activities as a senior officer and director of the Company was privy to and participated in the analysis of rimonabant clinical trials, regulatory filings and reporting regarding rimonabant; (c) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the serious adverse effects associated with rimonabant, at all relevant times; and (d) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading and omitted material information.

159. In addition to the duties of full disclosure imposed on defendants as a result of their making of affirmative statements and reports, or participation in the making of affirmative statements and reports to the investing public, defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-X, 17 C.F.R. §§210.01, *et seq.*, and Regulation S-K, 17 C.F.R. §§229.10, *et seq.*, and other SEC regulations, including accurate and truthful information with respect to rimonabant so that the market price of the Company's securities would be based on truthful, complete and accurate information.

160. The defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were made knowingly or with a reckless disregard for the truth and for the purpose and effect of concealing the serious adverse effects associated with rimonabant and supporting the artificially inflated prices of the Company's publicly traded securities.

161. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Sanofi's publicly traded securities were artificially inflated during the Class Period. In ignorance of the fact that the market price of Sanofi's publicly traded securities was artificially inflated, and relying directly or indirectly on the false and misleading statements made by defendants, or upon the integrity of the markets in which the securities trade and/or on the absence of material adverse information that was known to or recklessly disregarded by defendants, but not disclosed in public statements by defendants during the Class Period, plaintiffs and the other members of the Class acquired Sanofi publicly traded

securities during the Class Period at artificially inflated prices and were damaged when the artificial inflation came out of the securities.

162. At the time of said misrepresentations and omissions, plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had plaintiffs, the other members of the Class and the marketplace known the truth regarding the serious adverse effects associated with rimonabant which were not disclosed by defendants, plaintiffs and other members of the Class would not have purchased or otherwise acquired their Sanofi publicly traded securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

163. By virtue of the foregoing, defendants have violated §10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

164. As a direct and proximate result of defendants' wrongful conduct, plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's publicly traded securities during the Class Period.

COUNT II

Violation of Section 20(a) of the Exchange Act Against All Defendants

165. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

166. The individual defendants acted as controlling persons of Sanofi within the meaning of §20(a) of the Exchange Act as alleged herein. Sanofi controlled all of its employees and each of the individual defendants. By virtue of their high-level positions, and their ownership and contractual rights, participation in and awareness of the Company's operations and intimate knowledge of the false statements and omissions made by the Company and disseminated to the

investing public, the individual defendants had the power to influence and control and did influence and control, directly or indirectly, the decision making of the Company, including the content and dissemination of the various statements which plaintiffs contend are false and misleading. The individual defendants participated in conference calls with investors and were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements, alleged by plaintiffs to be misleading, prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

167. In particular, each of these defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

168. As set forth above, Sanofi and the individual defendants each violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this complaint. By virtue of their positions as controlling persons, defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of defendants' wrongful conduct, plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's publicly traded securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs respectfully pray for relief and judgment, as follows:

A. Determining that this action is a proper class action, and certifying plaintiffs as class representatives under Federal Rule of Civil Procedure 23;

B. Awarding compensatory damages in favor of plaintiffs and the other members of the Class against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

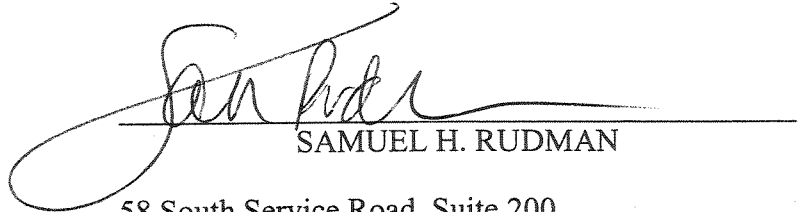
D. Such equitable, injunctive or other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury.

DATED: April 29, 2008

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Lead Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I, Kelly Stadelmann, hereby certify that on April 29, 2008, I caused a true and correct copy of the attached: CONSOLIDATED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS to be served via United States mail on:

Lewis J. Liman, Esq.
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Kelly Stadelmann